NOTICE OF OFFICE OF MANAGEMENT AND BUDGET ACTION

Madeleine Clayton 06/17/2002
Departmental Forms Clearance Officer
Office of the Chief Information Officer
14th and Constitution Ave. NW.
Room 6086
Washington, DC 20230

In accordance with the Paperwork Reduction Act, OMB has taken the following action on your request for approval of the reinstatement of an information collection received on 04/15/2002.

TITLE: Seafood Inspection and Certification Requirements

AGENCY FORM NUMBER(S): 89-800,89-814,89-819

ACTION : APPROVED WITHOUT CHANGE
OMB NO.: 0648-0266
EXPIRATION DATE: 06/30/2005

BURDEN:	RESPONSES	HOURS	COSTS($,000)
Previous	0	0	0
New	7,082	13,065	3
Difference	7,082	13,065	3
Program Change		13,065	3
Adjustment		0	0

TERMS OF CLEARANCE: None

OMB Authorizing Official Title

Donald R. Arbuckle Deputy Administrator, Office of Information and Regulatory Affairs

PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the supporting statement, and any additional documentation to: Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

1. Agency/Subagency originating request
DOC/NOAA/NMFS

2. OMB control number b. [ ] None
a. 0648 - 0266

3. Type of information collection (*check one*)
a. [ ] New Collection
b. [ ] Revision of a currently approved collection
c. [ ] Extension of a currently approved collection
d. [✔] Reinstatement, without change, of a previously approved collection for which approval has expired
e. [ ] Reinstatement, with change, of a previously approved collection for which approval has expired
f. [ ] Existing collection in use without an OMB control number
For b-f, note Item A2 of Supporting Statement instructions

4. Type of review requested (*check one*)
a. [✔] Regular submission
b. [ ] Emergency - Approval requested by ____/____/____
c. [ ] Delegated

5. Small entities
Will this information collection have a significant economic impact on a substantial number of small entities? [ ] Yes [✔] No

6. Requested expiration date
a. [✔] Three years from approval date b. [ ] Other Specify: ____/____

7. Title Seafood Inspection and Certification Requirements

8. Agency form number(s) (*if applicable*) NOAA Forms 89-800, 89-814, 89-819

9. Keywords 'seafood, food grades and standards'

10. Abstract

NOAA operates a voluntary fee-for-service seafood inspection program. Federally-inspected products may display official quality grade marks. Those wishing to participate in the program must request the services and submit specific compliance information.

11. Affected public (*Mark primary with "P" and all others that apply with "x"*)
a. ___ Individuals or households d. ___ Farms
b. P Business or other for-profit e. ___ Federal Government
c. ___ Not-for-profit institutions f. ___ State, Local or Tribal Government

12. Obligation to respond (*check one*)
a. [ ] Voluntary
b. [✔] Required to obtain or retain benefits
c. [ ] Mandatory

13. Annual recordkeeping and reporting burden
a. Number of respondents 7,082
b. Total annual responses 7,082
1. Percentage of these responses collected electronically 0 %
c. Total annual hours requested 13,065
d. Current OMB inventory 0
e. Difference 13,065
f. Explanation of difference
1. Program change 13,065
2. Adjustment

14. Annual reporting and recordkeeping cost burden *(in thousands of dollars)*
a. Total annualized capital/startup costs 0
b. Total annual costs (O&M) 3
c. Total annualized cost requested 3
d. Current OMB inventory 0
e. Difference 3
f. Explanation of difference
1. Program change 3
2. Adjustment

15. Purpose of information collection (*Mark primary with "P" and all others that apply with "X"*)
a. P Application for benefits e. x Program planning or management
b. x Program evaluation f. ___ Research
c. ___ General purpose statistics g. ___ Regulatory or compliance
d. ___ Audit

16. Frequency of recordkeeping or reporting *(check all that apply)*
a. [✔] Recordkeeping b. [ ] Third party disclosure
c. [✔] Reporting
1. [✔] On occasion 2. [ ] Weekly 3. [ ] Monthly
4. [ ] Quarterly 5. [ ] Semi-annually 6. [ ] Annually
7. [ ] Biennially 8. [ ] Other (describe) ____

17. Statistical methods
Does this information collection employ statistical methods
[ ] Yes [✔] No

18. Agency Contact (person who can best answer questions regarding the content of this submission)
Name: Rita Creitz
Phone: 301-713-2355

19. Certification for Paperwork Reduction Act Submissions

On behalf of this Federal Agency, I certify that the collection of information encompassed by this request complies with 5 CFR 1320.9

NOTE: The text of 5 CFR 1320.9, and the related provisions of 5 CFR 1320.8(b)(3), appear at the end of the instructions. *The certification is to be made with reference to those regulatory provisions as set forth in the instructions.*

The following is a summary of the topics, regarding the proposed collection of information, that the certification covers:

(a) It is necessary for the proper performance of agency functions;

(b) It avoids unnecessary duplication;

(c) It reduces burden on small entities;

(d) It used plain, coherent, and unambiguous terminology that is understandable to respondents;

(e) Its implementation will be consistent and compatible with current reporting and recordkeeping practices;

(f) It indicates the retention period for recordkeeping requirements;

(g) It informs respondents of the information called for under 5 CFR 1320.8(b)(3):

(i) Why the information is being collected;

(ii) Use of information;

(iii) Burden estimate;

(iv) Nature of response (voluntary, required for a benefit, mandatory);

(v) Nature and extent of confidentiality; and

(vi) Need to display currently valid OMB control number;

(h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected (see note in Item 19 of instructions);

(i) It uses effective and efficient statistical survey methodology; and

(j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of the provisions, identify the item below and explain the reason in Item 18 of the Supporting Statement.

Signature of Senior Official or designee	Date

Agency Certification (signature of Assistant Administrator, Deputy Assistant Administrator, Line Office Chief Information Officer, head of MB staff for L.O.s, or of the Director of a Program or StaffOffice)	
Signature signed by Rebecca Lent	Date 3/29/2002
Signature of NOAA Clearance Officer	
Signature signed by Richard Roberts	Date 4/05/2002

SUPPORTING STATEMENT
SEAFOOD INSPECTION AND CERTIFICATION REQUIREMENTS
OMB CONTROL NO. 0648-0266

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary.

The National Marine Fisheries Service (NMFS) operates a voluntary fee-for-service seafood inspection program (Program) under the authorities of the Agricultural Marketing Act of 1946, as amended, the Fish and Wildlife Act of 1956, and Reorganization Plan No. 4 of 1970. The regulations for the Program are contained in 50 CFR Part 260. The program offers inspection grading, and certification services, including the use of official quality grade marks which indicate that specific products have been Federally inspected. In addition, the NMFS inspection program is the only Federal entity which establishes quality grade standards for seafood marketed in the United States. Qualified participants are permitted to use the program's official quality grade marks on their products to facilitate trade of fishery products.

2. Explain how, by whom, how frequently, and for what purpose the information will be used.

Participants in the Program include all segments of the seafood industry from harvesters to retailers. When inspection services are desired, participants are requested to submit specific information pertaining to the type of inspection service needed [§260.15]. That is, applicants provide the Program information regarding the type of products to be inspected, the quantity, the location of the product, and the date when the inspection is needed. There are also application requirements (i.e., a letter from the participant) if there is an appeal on previous inspection results [§260.36]. Participants requesting regular inspection services on a contractual basis submit a contract [§260.96]. Any changes to the contract require a contract amendment, using the same form. Participants interested in using official grade marks are required to submit product labels and specifications for review and approval to ensure compliance with mandatory labeling regulations established by the U.S. Food and Drug Administration as well as proper use of the Program's marks [§260.97(c)(12), (13), (14) and (15)].

Current regulations state requirements for approval of drawings and specifications prior to approval of facilities [§260.96(b) and (c)]. There are no respondents under this section. The Program will amend this part of the regulations in a future action.

In July 1992, NMFS announced new inspection services, which were fully based on guidelines recommended by the National Academy of Sciences, known as Hazard Analysis Critical Control Point (HACCP). The information collection requirements fall under §260.15 of the regulations. These guidelines required that a facility's quality control system have a written plan of the operation, identification of control points with acceptance criteria and a corrective action plan, as well as identified personnel responsible for oversight of the system. The attachment entitled

"Development, Assessment, Approval, and Continuing Compliance Evaluation of HACCP-based Inspection Systems", a chapter from the NMFS Fishery Products Inspection Manual, describes in detail the requirements for participants choosing to receive NMFS HACCP-based inspection services.

HACCP requires continuing monitoring and record keeping by the facility's personnel. Although HACCP involves substantial self-monitoring by the industry, the HACCP-based program is not a self-certification program. It relies on unannounced system audits by NMFS. The frequency of audits is determined by the ability of the firm to monitor its operation. By means of these audits, NMFS reviews the records produced through the program participant's self-monitoring. The audits determine whether the participant's HACCP-based system is in compliance by checking for overall sanitation, accordance with good manufacturing practices, labeling, and other requirements. In addition, in-process reviews, end-product sampling, and laboratory analyses are performed by NMFS at frequencies based on the potential consumer risk associated with the product and/or the firm's history of compliance with the program's criteria.

The information collected is used to determine a participant's compliance with the program. The reported information, a HACCP plan, is needed only once. Other information is collected and kept by the participant as part of its routine monitoring activities. NMFS audits the participant's records on unannounced frequencies to further determine compliance.

The U.S. Food and Drug Administration (FDA) implemented mandatory HACCP seafood safety requirements in December 1997. The FDA regulations [21 CFR Part 123] include some of the same reporting elements as the NMFS HACCP program. However, one of the significant differences is that the FDA regulation is mandatory for seafood processors and focuses on seafood safety only. The NMFS HACCP program is voluntary, is available to all segments of the seafood industry (from harvesters to retailers), and addresses not only seafood safety, but also wholesomeness (hygiene), economic integrity and seafood quality. There is a NMFS HACCP mark available to participants to assist them in marketing their products. FDA's mandatory program has no mark. Further, the FDA regulations require a HACCP plan only if a hazard analysis reveals a seafood safety hazard. NMFS requires a HACCP plan for all participants in the HACCP Program. The NMFS HACCP program also assures participants compliance with international trade standards. Attached is a table illustrating the differences between the FDA and NMFS HACCP programs.

The burden hours identified are those beyond the FDA's mandatory HACCP requirements to ensure seafood safety. HACCP-related burden hours are identified separately below and are based on an estimate of 30 new HACCP facilities a year and include annual monitoring and record keeping estimates for 100 facilities already in the Program.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology.

The information collected does not involve the use of automated, electronic or other technological techniques. Much of the information for inspection requests is gathered over the phone and documented by the Program's inspection personnel. Examples of labels and specifications are generally submitted in hard copy to the Program's review staff for approval. Electronic submissions, via attachments to email, for example, are also acceptable. The form for Request for Inspection Services may be printed off the Program's Website.

4. Describe efforts to identify duplication.

As mentioned in Item 2, the FDA HACCP regulations require some of the same reporting elements as the NMFS HACCP program. This statement includes reporting burden beyond what is required under the FDA regulations to better ensure seafood safety. In other words, an applicant's NMFS HACCP plan is acceptable under the FDA regulations so that no additional plan is needed for FDA. If, however, the applicant wishes to participant in the NMFS HACCP program and has an FDA HACCP plan, the FDA HACCP plan would be expanded to include the NMFS requirements which address not only seafood safety, but also wholesomeness (hygiene), economic fraud, and seafood quality.

5. If the collection of information involves small businesses or other small entities, describe the methods used to minimize burden.

Small businesses may voluntarily participate in the Program and respond to the collection. Specific instructions are provided, where needed, to all businesses to prevent submission of unnecessary information and to minimize the burden.

6. Describe the consequences to the Federal program or policy activities if the collection is not conducted or is conducted less frequently.

If the collection were not conducted, efficient operation of the Program would be jeopardized and would less serve the customers for whom it is intended.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with OMB guidelines.

For participants to continue to obtain the benefits of advertising the official Program marks and to ensure the Program's marks are being used with integrity, some of the collections are done at a frequency inconsistent with the OMB guidelines. For example, HACCP participants submit their HACCP plan only once, but changes in the plan may occur whenever their processing operations dictate, which may be outside of the OMB guidelines. In addition, monitoring of the HACCP plan is an ongoing activity which is then audited by Program personnel at varying frequencies to determine the participant's compliance with the Program requirements.

The regulations for label approval [§260.97(b)(13) and (15)] require one more copy than recommended by OMB. The labels, once approved, are distributed to the applicant, the

inspector in the facility, the regional inspection office, and the label approving officer for their records and future reference, which can be critical particularly if there is a question or dispute.

8. Provide a copy of the PRA Federal Register notice that solicited public comments on the information collection prior to this submission. Summarize the public comments received in response to that notice and describe the actions taken by the agency in response to those comments. Describe the efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

A copy of the PRA Federal Register notice is attached. No public comments were received.

9. Explain any decisions to provide payments or gifts to respondents, other than remuneration of contractors or grantees.

No payments or gifts are made.

10. Describe any assurance of confidentiality provided to respondents and the basis for assurance in statute, regulation, or agency policy.

Participants in the Program are assured of the confidentiality of certain information, such as records of sanitation and HACCP plans, which may contain privileged trade information. The Department of Commerce, with the concurrence of the U.S. Department of Justice, determined that this information is protected from disclosure pursuant to the Freedom of Information Act Exemption (b)(4), 5 U.S.C. § 552(b)(4), which applies to trade secrets and commercial or financial information obtained from a person that is privileged or confidential.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

No sensitive questions are asked.

12. Provide an estimate in hours of the burden of the collection of information.

Estimated Number of Respondents, Response Times, and Total Burden. The estimates below are based on anecdotal data from Program personnel who estimated the average annual salary of Program participants to be around $35,000.

§260.15 Application for Inspection Services. The estimated time per response is an average based on the wide range of applicants. Regular applicants, for example, have made extra copies of the form with the standard information completed so that they simply fill in several additional blocks, which would likely require much less than 5 minutes, then fax it to the inspection office. New applicants, on the other hand, may take longer. They may provide the information over the

phone or we may fax them a blank form which they complete and fax in return. Also, not all of the blocks on the form are required to be completed before inspection services can be provided. Missing information may be inserted by the inspector at a later date and kept as an internal record.

Estimated Number of Respondents: 6,952
Estimated Time Per Response: 5 minutes
Estimated Total Annual Burden Hours: 579
Estimated Total Annual Cost to Respondent: $9,843

§260.36 Application for Appeal. As mentioned in Item 2, this is simply a short letter notifying the inspection office that an appeal is requested.

Estimated Number of Respondents: 75
Estimated Time Per Response: 5 minutes
Estimated Total Annual Burden Hours: 6
Estimated Total Annual Cost to Respondent: $102

§260.96 Contract Completion. This estimate includes new applicants, estimated at about 35 annually, and current participants who amend their contracts during the year. The burden estimate is considered equal for both situations.

Estimated Number of Respondents: 215
Estimated Time Per Response: 5 minutes
Estimated Total Annual Burden Hours: 18
Estimated Total Annual Cost to Respondent: $303

§260.96(b) and (c) Drawing and Floor Plan Approval

Estimated Number of Respondents: 0
Estimated Time Per Response: 0 minutes
Estimated Total Annual Burden Hours: 0
Estimated Total Annual Cost to Respondent: $0

§260.97(c)(12), (13), and (15) Label and Specification Submission. This estimate includes not only completing the form, but also the estimate to develop a new specification or revise an existing one. The estimate also includes the time to compile, duplicate, and package the submission.

Estimated Number of Respondents: 2,624
Estimated Time Per Response: 30 minutes
Estimated Total Annual Burden Hours: 1312
Estimated Total Annual Cost to Respondent: $22,077

HACCP Participants

New Respondents. These are applicants that are not currently in the NMFS HACCP Program, who need to develop a NMFS HACCP Plan, which as explained previously, is required only once. It is possible that if the applicant has an FDA HACCP plan, expansion of it to include NMFS requirements may take a little less time. The burden reflected considers both situations equal.

Estimated Number of Respondents: 30
Estimated Time Per Response: 105 hours
Estimated Total Annual Burden Hours: 3,150
Estimated Total Annual Cost to Respondent: $53,550

Current Respondents. These are participants already in the NMFS HACCP Program, with an operating HACCP Plan. These participants are responsible for certain monitoring and record keeping functions as described in the attached manual release, and is included in the estimate below.

Estimated Number of Respondents: 100
Estimated Time Per Response: 80 hours
Estimated Total Annual Burden Hours: 8,000
Estimated Total Annual Cost to Respondent: $136,000

TOTAL RESPONDENTS: 9,996
TOTAL BURDEN HOURS: 13,065
TOTAL COST TO RESPONDENTS: $221,875

13. Provide an estimate of the total annual cost burden to the respondents or record-keepers resulting from the collection.

Some of the information is faxed and some is mailed. The combined annual costs for copying, faxing, or mailing is $3,500.

14. Provide estimates of annualized cost to the Federal government.

As a fee-for-service Program as explained in Item 1, all of the costs to the Federal government for the collection are paid by the respondents.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB 83-I.

The program changes result from a reinstatement of OMB approval which had expired.

16. For collections whose results will be published, outline the plans for tabulation and publication.

Results are not published.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons why display would be inappropriate.

Not applicable.

18. Explain each exception to the certification statement identified in Item 19 of the OMB 83-I.

Not applicable.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection does not employ statistical methods

OMB Control #0648-0266
Expires_____

NOAA form 89-814
Prescribed by NOAA Inspection Manual 25
(draft 11-8-99)

U.S. DEPARTMENT OF COMMERCE
NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION

REQUEST FOR INSPECTION SERVICES

CONTRACT NUMBER:

FEDERAL TAX ID # :

TODAY'S DATE:

NAME OF REQUESTER			SERVICING AGENT'S NAME/PHONE NUMBER		
STREET ADDRESS			STREET ADDRESS		
CITY	STATE	ZIP CODE	CITY	STATE	ZIP CODE
CONTACT NAME	PHONE NO.	FAX NO.	TYPE INSPECTION REQUESTED **___ Lot Inspection Certificate** **___ Export Health Certificate** **___ Certificate of Origin** **___ EU Certificate** **___ Other:**		
LOCATION OF PRODUCTS – NAME					
LOCATION OF PRODUCTS – STREET ADDRESS					
CITY	STATE	ZIP CODE	SPECIAL INSTRUCTIONS *(Buyer Specifications, country requirements, etc)* **___ Market Specifications:** **___ Product on FDA Hold?**		
ASSESS CHARGES TO:					
STREET ADDRESS Same			DISPOSITION OF SAMPLES: **___ Return ___ Destroy ___ Charity**		
CITY	STATE	ZIP CODE	INSPECT FOR: **___ Quality & Condition** **___ Minimum U.S. Grade Attributes** **___ U.S. Grade A Attributes** **___ Net Weight** **___ Size or Count** **___ Other: ___origin_____**		
CERTIFICATE FORWARDED TO:					
STREET ADDRESS Same					
CITY	STATE	ZIP CODE			

REMARKS

LOT NUMBER	BRAND	PRODUCT	NUMBER OF CARTONS / CASES & SIZE	TOTAL POUNDS

NAME OF SHIPPER *(For export only)*		NAME OF CONSIGNEE *(For export only)*
ADDRESS		ADDRESS
PORT OF EXPORT	VESSEL OR AIRLINE	PORT OF DESTINATION
APPLICANT *(Printed Name & Signature)*		DATE

Information Collection Notification – NOAA Form 89-814

This information collection is authorized under 50 CFR §260.15. The information will be used to record applicants requesting inspection services on non-contractual basis. Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of the collection of information, including suggestions for reducing this burden to the Seafood Inspection Program, 1315 East-West Highway, Silver Spring, MD 20910. This information is required in order to receive inspection services on non-contract basis.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB control Number.

OMB Control #0648-0266
Expires _____

NOAA FORM 89-819
PRESCRIBED BY INSPECTION MANUAL 25
(05-99)

U.S. DEPARTMENT OF COMMERCE
NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION
NATIONAL SEAFOOD INSPECTION PROGRAM

1. DATE SUBMITTED

2. PLANT CODE(S)

SPECIFICATION AND LABEL SUBMITTAL ACTION REQUEST

INSTRUCTIONS - Please print or complete by typewriter. Submit a set of 5 specifications and/or labels with each product label indicated on form. All copies except field copy are to be submitted to the address below for action. Field copy to be retained by requestor until specifications and/or labels are returned by Approving Officer.

3. PROCESSOR OR PACKER *(Name, Address and Phone Number)*

TO: National Seafood Inspection Program
Documentation Approval and Supply Services Section
3207 Frederic Street, Suite B
P.O. Drawer 1207
Pascagoula, MS 39568-1207

4. DISTRIBUTOR *(Name and full address)*

USDC No. (Item 5) to be assigned by Approving Officer. Indicate USDC No. of approved specifications or labels in Remarks when submitting replacements with minor changes, or when submitting for verification or cancellation. Indicate primary logo, packer or distributor name, or other indentification for item 6. Use numbers only for item 9: 1 - No. Shield, 2 - Combination Grade A & PUFI., 3 - PUFI Mark, 4 - Grade A, 5 - Lot Inspected Mark.

5. USDC NO.		6. PRODUCT IDENTIFICATION (Brand and identifying numbers if any)	7. COMMODITY *(Use official terminology including type, style and size; indicate in ounces or count/pounds. Enter 10 digit commodity code)*		8. CONTENT OR NET WT.	9. SHIELD CODE *(See Above)*
LABEL	SPEC.		Product	Commodity Code		

10. USDC INSPECTOR *(Signature)* Inspector No. _____ HACCP ☐

COMPANY OFFICIAL *(Signature)*

11. HAVE SPECIFICATIONS AND/OR LABELS BEEN REVIEWED FOR COMPLIANCE WITH USDC AND FDA REGULATIONS?
BY INSPECTOR? YES ☐ NO ☐ BY FIELD INSPECTION OFFICER? YES ☐ NO ☐

12. ACTION REQUESTED ☐ LABEL/SPEC. REVIEW ☐ NEW LABEL SKETCH/PROOF REVIEW ☐ NEW LABEL APPROVAL *(Final)*
☐ NEW SPEC. APPROVAL *(Final)* ☐ REPLACEMENT SPEC. OR LABEL ☐ CANCEL APPROVAL ☐ OTHER *(Specify in remarks.)*
☐ USDA/FNS (CN) LABEL OR SPECS ACTION ☐ EXTEND TEMPORARY APPROVAL *(Specify reason in remarks)*

APPROVAL BY THE USDC IS BASED ON THE INFORMATION SUPPLIED AND DOES NOT IMPLY CONCURRENCE OR ACCEPTANCE BY OTHER FEDERAL STATE OR LOCAL GOVERNMENTAL AGENCIES UNLESS SPECIFICALLY NOTED, NOR DOES IT RELIEVE THE COMPANY FROM COMPLIANCE WITH OTHER APPLICABLE LAWS, REGULATIONS OR RULINGS. THIS APPROVAL BECOMES VOID IF CHANGES ARE MADE IN THE SPECIFICATION OR LABEL WITHOUT THE CONCURRENCE OF THE USDC APPROVING OFFICER.

13. REMARKS *(Please initial)*

TO BE COMPLETED BY APPROVING OFFICE(S) ONLY

PROOF APPROVED FOR PRINTING ☐ AS IS ☐ WITH CHANGES NOTED
☐ TEMPORARY APPROVAL EXPIRES (SPEC) _____ (LABEL) _____
☐ FINAL APPROVAL LABEL ☐ FINAL APPROVAL SPEC ☐ EXTENDS APPROVAL
☐ DISAPPROVED LABEL ☐ DISAPPROVED SPEC ☐ CANCELLED
☐ REVIEWED

APPROVING OFFICER *(Signature)* DATE

USDA/FNS USE ONLY ☐ SKETCH/PROOF
☐ LABEL ☐ CONCURRENCE ☐ NON-CONCURRENCE
USDA APPROVAL *(Signature)* DATE

NOAA FORM 89-819

*U.S. GPO: 1999-452-531/25005

ORIGINAL

INFORMATION COLLECTION NOTIFICATION
NOAA Form 88-819

This information collection is authorized under 50 CFR §260.97(c)(12), (13), and (15). The information will be used to ensure compliance with mandatory labeling regulations established by the U.S. Food and Drug Administration as well as the proper used of the official marks of the voluntary National Seafood Inspection Program. Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of the collection of information, including suggestions for reducing this burden, to the National Seafood Inspection Program, 1315 East-West Highway, Silver Spring, MD 20910. This information is required in order to obtain the benefits of the use of official marks [50 CFR §260.86].

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB Control Number.

OMB Control No. 0648-0266
Expires _____

NOAA FORM 89-800 (5-85) Prescribed by Handbook 25 U.S. DEPARTMENT OF COMMERCE NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION NATIONAL MARINE FISHERIES SERVICE	CONTRACT NO.
CONTRACT OF AGREEMENT FOR: G **IN-PLANT INSPECTION SERVICE** G **REGULAR** G **PLANT/VESSEL SANITATION SERVICE** G **FEDERAL** G **LOT INSPECTION** **PROCUREMENT**	DATE OF: G CONTRACT G AMEND. G ADD.
	ABOVE FOR AGENCY USE ONLY

We, _____ located at _____, hereby make application for a G a contract G an amendment to our contract G an addendum to our contract for inspection services as follows:

LOCATION OF OFFICIAL ESTABLISHMENT/ OLD STORAGE/DRY STORAGE	**PRODUCTS COVERED**

1. Sanitation and/or Inspection service to commence on _____ or as soon thereafter as appears practicable to the National Marine Fisheries Service, National Oceanic and Atmospheric Administration, United States Department of Commerce (Hereafter referred to as NMFS).

2.. NMFS will furnish the services of Federal inspectors to make the inspection of the aforementioned G sanitation and/or G processed food products at the aforesaid designated official establishment and also furnish inspection reports in accordance with the applicable regulations of NMFS at the time such service is rendered.

3. The applicant agrees to _____ minimum hours of inspection per week/month, at the currently established rates for the type of services rendered.

4. The Regulations contained in Part 260 of Title 50 CFR are hereby incorporated by reference and a copy is attached hereto. The Applicant agrees to all the provisions, conditions, and requirements set forth in the regulations and instructions contained in the Inspection Manual for the type of services rendered.

5. Upon approval of ths application by NMFS, it shall constitute G a contract G an amendment G an addendum to contract no. _____ between the undersigned applicant and NMFS in accordance with the terms and conditions provided herein.

6. Additional provisions to this contract are G attached hereto G continued on the reverse.

APPLICANT	**APPROVAL**
NAME	NATIONAL MARINE FISHERIES SERVICE
SIGNATURE	SIGNATURE OF APPROVING OFFICER
TITLE	TITLE
DATE	DATE

SUPERSEDES NOAA FORMS 89-800 (10-73), AND 89-829 (3-74).

INFORMATION COLLECTION NOTIFICATION
NOAA Form 88-800

This information collection is authorized under 50 CFR §260.96. The information will be used to register participants requesting regular inspection services on a contractual basis. Any change to the contract require a contract amendment, using this form. Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of the collection of information, including suggestions for reducing this burden, to the National Seafood Inspection Program, 1315 East-West Highway, Silver Spring, MD 20910. This information is required in order to receive inspection services on a contract basis.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB Control Number.

SUBCHAPTER G—PROCESSED FISHERY PRODUCTS, PROCESSED PRODUCTS THEREOF, AND CERTAIN OTHER PROCESSED FOOD PRODUCTS

PART 260—INSPECTION AND CERTIFICATION

Subpart A—Inspection and Certification of Establishments and Fishery Products for Human Consumption

AUTHORITY: Sec. 6, 70 Stat. 1122, 16 U.S.C. 742e; secs. 203, 205, 60 Stat. 1087, 1090 as amended; 7 U.S.C. 1622, 1624; Reorganization Plan No. 4 of 1970 (84 Stat. 2090).

SOURCE: 31 FR 16052, Dec. 15, 1966, unless otherwise noted.

Subpart A—Inspection and Certification of Establishments and Fishery Products for Human Consumption

§ 260.1 Administration of regulations.

The Secretary of Commerce is charged with the administration of the regulations in this part except that he may delegate any or all of such functions to any officer or employee of the National Marine Fisheries Service of the Department in his discretion.[1]

[36 FR 21037, Nov. 3, 1971]

DEFINITIONS

§ 260.6 Terms defined.

Words in the regulations in this part in the singular form shall be deemed to import the plural and vice versa, as the case may demand. For the purposes of the regulations in this part, unless the context otherwise requires, the following terms shall have the following meanings:

Acceptance number. ''Acceptance number'' means the number in a sampling plan that indicates the maximum number of deviants permitted in a sample of a lot that meets a specific requirement.

Act. ''Act'' means the applicable provisions of the Agricultural Marketing Act of 1946 (60 Stat. 1087 et seq., as amended; 7 U.S.C. 1621 et seq.).

Applicant. ''Applicant'' means any interested party who requests inspection service under the regulations in this part.

Case. ''Case'' means the number of containers (cased or uncased) which, by the particular industry are ordinarily packed in a shipping container.

Certificate of loading. ''Certificate of loading'' means a statement, either written or printed, issued pursuant to the regulations in this part, relative to check-loading of a processed product subsequent to inspection thereof.

Certificate of sampling. ''Certificate of sampling'' means a statement, either written or printed issued pursuant to the regulations in this part, identifying officially drawn samples and may include a description of condition of containers and the condition under which the processed product is stored.

Class. ''Class'' means a grade or rank of quality.

Condition. ''Condition'' means the degree of soundness of the product which may affect its merchantability and includes, but is not limited to those factors which are subject to change as a result of age, improper preparation and processing, improper packaging, improper storage, or improper handling.

Department. ''Department'' means the U.S. Department of Commerce.

Deviant. ''Deviant'' means a sample unit affected by one or more deviations or a sample unit that varies in a specifically defined manner from the requirements of a standard, specification, or other inspection document.

Deviation. ''Deviation'' means any specifically defined variation from a particular requirement.

Director. ''Director'' means the Director of the National Marine Fisheries Service.

[1] All functions of the Department of Agriculture which pertain to fish, shellfish, and any products thereof, now performed under the authority of title II of the Act of August 14, 1946, popularly known as the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621–1627) including but not limited to the development and promulgation of grade standards, the inspection and certification, and improvement of transportation facilities and rates for fish and shellfish and any products thereof, were transferred to the Department of the Interior by the Director of the Budget (23 FR 2304) pursuant to section 6(a) of the Act of Aug. 8, 1956, popularly known as the Fish and Wildlife Act of 1956 (16 U.S.C. 742e). Reorganization Plan No. 4 of 1970 (84 Stat. 2090) transferred, among other things, such functions from the U.S. Department of the Interior to the U.S. Department of Commerce.

Establishment. ''Establishment'' means any premises, buildings, structures, facilities, and equipment (including vehicles) used in the processing, handling, transporting, and storage of fish and fishery products.

Inspection certificate. ''Inspection certificate'' means a statement, either written or printed, issued pursuant to the regulations in this part, setting forth in addition to appropriate descriptive information relative to a processed product, and the container thereof, the quality and condition, or any part thereof, of the product and may include a description of the conditions under which the product is stored.

Inspection service. ''Inspection service'' means:

(1) The sampling pursuant to the regulations in this part;

(2) The determination pursuant to the regulations in this part of:

(i) Essential characteristics such as style, type, size, or identity of any processed product which differentiates between major groups of the same kind;

(ii) The class, quality, and condition of any processed product, including the condition of the container thereof by the examination of appropriate samples;

(3) The issuance of any certificate of sampling, inspection certificates, or certificates of loading of a processed product, or any report relative to any of the foregoing; or

(4) Performance by an inspector of any related services such as to observe the preparation of the product from its raw state through each step in the entire process; or observe conditions under which the product is being harvested, prepared, handled, stored, processed, packed, preserved, transported, or held; or observe sanitation as a prerequisite to the inspection of the processed product, either on a contract basis or periodic basis; or checkload the inspected processed product in connection with the marketing of the product, or any other type of service of a consultative or advisory nature related herewith.

Inspector. ''Inspector'' means any employee of the Department authorized by the Secretary or any other person licensed by the Secretary to investigate, sample, inspect, and certify in accordance with the regulations in this part to any interested party the class, quality and condition of processed products covered in this part and to perform related duties in connection with the inspection service.

Interested party. ''Interested party'' means any person who has a financial interest in the commodity involved.

Licensed sampler. ''Licensed sampler'' means any person who is authorized by the Secretary to draw samples of processed products for inspection service, to inspect for identification and condition of containers in a lot, and may, when authorized by the Secretary, perform related services under the act and the regulations in this part.

Lot. ''Lot'' has the following meanings:

(1) For the purpose of charging fees and issuing certificates, ''Lot'' means any number of containers of the same size and type which contain a processed product of the same type and style located in the same or adjacent warehouses and which are available for inspection at any one time: *Provided,* That:

(i) Processed products in separate piles which differ from each other as to grade or other factors may be deemed to be separate lots;

(ii) Containers in a pile bearing an identification mark different from other containers of such processed product in that pile, if determined to be of lower grade or deficient in other factors, may be deemed to be a separate lot; and

(iii) If the applicant requests more than one inspection certificate covering different portions of such processed product, the quantity of the product covered by each certificate shall be deemed to be a separate lot.

(2) For the purpose of sampling and determining the grade or compliance with a specification, ''Lot'' means each pile of containers of the same size and type containing a processed product of the same type and style which is separated from other piles in the same warehouse, but containers in the same pile bearing an identification mark different from other containers in that

pile may be deemed to be a separate lot.

Official establishment. ''Official establishment'' means any establishment which has been approved by National Marine Fisheries Service, and utilizes inspection service on a contract basis.

Officially drawn sample. ''Officiallydrawn sample'' means any sample that has been selected from a particular lot by an inspector, licensed sampler, or by any other person authorized by the Secretary pursuant to the regulations in this part.

Person. ''Person'' means any individual, partnership, association, business trust, corporation, any organized group of persons (whether incorporated or not), the United States (including, but not limited to, any corporate agencies thereof), any State, county, or municipal government, any common carrier, and any authorized agent of any of the foregoing.

Plant. ''Plant'' means the premises, buildings, structures, and equipment (including, but not being limited to, machines, utensils, and fixtures) employed or used with respect to the manufacture or production of processed products.

Processed product. ''Processed product'' means any fishery product or other food product covered under the regulations in this part which has been preserved by any recognized commercial process, including, but not limited to, canning, freezing, dehydrating, drying, the addition of chemical substances, or by fermentation.

Quality. ''Quality'' means the inherent properties of any processed product which determine the relative degree of excellence of such product, and includes the effects of preparation and processing, and may or may not include the effects of packing media, or added ingredients.

Rejection number. ''Rejection number'' means the number in a sampling plan that indicates the minimum number of deviants in a sample that will cause a lot to fail a specific requirement.

Sample. ''Sample'' means any number of sample units to be used for inspection.

Sample unit. ''Sample unit'' means a container and/or its entire contents, a portion of the contents of a container or other unit of commodity, or a composite mixture of a product to be used for inspection.

Sampling. ''Sampling'' means the act of selecting samples of processed products for the purpose of inspection under the regulations in this part.

Secretary. ''Secretary'' means the Secretary of the Department or any other officer or employee of the Department authorized to exercise the powers and to perform the duties of the Secretary in respect to the matters covered by the regulations in this part.

Shipping container. ''Shipping container'' means an individual container designed for shipping a number of packages or cans ordinarily packed in a container for shipping or designed for packing unpackaged processed products for shipping.

Unofficially drawn sample. ''Unofficially drawn sample'' means any sample that has been selected by any person other than an inspector or licensed sampler, or by any other person not authorized by the Director pursuant to the regulations in this part.

Wholesome. ''Wholesome'' means the minimum basis of acceptability for human food purposes, of any fish or fishery product as defined in section 402 of the Federal Food, Drug, and Cosmetic Act, as amended.

[31 FR 16052, Dec. 15, 1966, as amended at 36 FR 21037, Nov. 3, 1971]

§260.7 Designation of official certificates, memoranda, marks, other identifications, and devices for purposes of the Agricultural Marketing Act.

Subsection 203(h) of the Agricultural Marketing Act of 1946 provides criminal penalties for various specified offenses relating to official certificates, memoranda, marks or other identifications and devices for making such marks or identifications, issued or authorized under section 203 of said act, and certain misrepresentations concerning the inspection or grading of agricultural products under said section. For the purposes of said subsection and the provisions in this part, the terms listed below shall have the respective meanings specified:

Official certificate. ''Official certificate'' means any form of certification, either written or printed, including those defined in § 260.6, used under this part to certify with respect to the inspection, class, grade, quality, size, quantity, or condition of products (including the compliance of products with applicable specifications).

Official device. ''Official device'' means a stamping appliance, branding device, stencil, printed label, or any other mechanically or manually operated tool that is approved by the Director for the purpose of applying any official mark or other identification to any product or the packaging material thereof.

Official identification. ''Official identification'' means any United States (U.S.) standard designation of class, grade, quality, size, quantity, or condition specified in this part or any symbol, stamp, label, or seal indicating that the product has been graded or inspected and/or indicating the class, grade, quality, size, quantity, or condition of the product approved by the Director and authorized to be affixed to any product, or affixed to or printed on the packaging material of any product.

Official mark. ''Official mark'' means the grade mark, inspection mark, combined form of inspection and grade mark, and any other mark, or any variations in such marks, including those prescribed in § 260.86, approved by the Secretary and authorized to be affixed to any product, or affixed to or printed on the packaging material of any product, stating that the product was graded or inspected or both, or indicating the appropriate U.S. Grade or condition of the product, or for the purpose of maintaining the identity of products graded or inspected or both under this part.

Official memorandum. ''Official memorandum'' means any initial record of findings made by an authorized person in the process of grading, inspecting, or sampling pursuant to this part, any processing or plant-operation report made by an authorized person in connection with grading, inspecting, or sampling under this part, and any report made by an authorized person of services performed pursuant to this part.

INSPECTION SERVICE

§ 260.12 Where inspection service is offered.

Inspection service may be furnished wherever an inspector or licensed sampler is available and the facilities and conditions are satisfactory for the conduct of such service.

§ 260.13 Who may obtain inspection service.

An application for inspection service may be made by any interested party, including, but not limited to, the United States and any instrumentality or agency thereof, any State, county, municipality, or common carrier, and any authorized agent in behalf of the foregoing.

§ 260.14 How to make application.

An application for inspection service may be made to the officer of inspection or to any inspector, at or nearest the place where the service is desired. An up-to-date list of the Inspection Field Offices of the Department may be obtained upon request to the Director. Satisfactory proof that the applicant is an interested party shall be furnished.

§ 260.15 Information required in connection with application.

Application for inspection service shall be made in the English language and may be made orally (in person or by telephone), in writing, or by telegraph. If an application for inspection service is made orally, such application shall be confirmed promptly in writing. In connection with each application for inspection service, there shall be furnished such information as may be necessary to perform an inspection on the processed product for which application for inspection is made, including but not limited to, the name of the product, name and address of the packer or plant where such product was packed, the location of the product, its lot or car number, codes or other identification marks, the number of containers, the type and size of the containers, the interest of the applicant in the product, whether the lot has been inspected previously to the application by any Federal agency and the purpose for which inspection is desired.

§ 260.16 Filing of application.

An application for inspection service shall be regarded as filed only when made in accordance with the regulations in this part.

§ 260.17 Record of filing time.

A record showing the date and hour when each application for inspection or for an appeal inspection is received shall be maintained.

§ 260.18 When application may be rejected.

An application for inspection service may be rejected by the Secretary (a) for noncompliance by the applicant with the regulations in this part, (b) for nonpayment for previous inspection services rendered, (c) when the product is not properly identifiable by code or other marks, or (d) when it appears that to perform the inspection service would not be to the best interests of the Government. Such applicant shall be promptly notified of the reason for such rejection.

§ 260.19 When application may be withdrawn.

An application for inspection service may be withdrawn by the applicant at any time before the inspection is performed: *Provided,* That, the applicant shall pay at the hourly rate prescribed in § 260.70 for the time incurred by the inspector in connection with such application, any travel expenses, telephone, telegraph or other expenses which have been incurred by the inspection service in connection with such application.

[31 FR 16052, Dec. 15, 1966, as amended at 36 FR 18738, Sept. 21, 1971]

§ 260.20 Disposition of inspected sample.

Any sample of a processed product that has been used for inspection may be returned to the applicant, at his request and expense; otherwise it shall be destroyed, or disposed of to a charitable institution.

§ 260.21 Basis of inspection and grade or compliance determination.

(a) Inspection service shall be performed on the basis of the appropriate U.S. standards for grades of processed products, Federal, Military, Veterans Administration or other government agency specifications, written contract specification, or any written specification or instruction which is approved by the Secretary.

(b) Unless otherwise approved by the Director compliance with such grade standards, specifications, or instructions shall be determined by evaluating the product, or sample, in accordance with the requirements of such standards, specifications, or instructions: *Provided,* That when inspection for quality is based on any U.S. grade standard which contains a scoring system the grade to be assigned to a lot is the grade indicated by the average of the total scores of the sample units: *Provided further,* That:

(1) Such sample complies with the applicable standards of quality promulgated under the Federal Food, Drug, and Cosmetic Act;

(2) Such sample complies with the product description;

(3) Such sample meets the indicated grade with respect to factors of quality which are not rated by score points; and

(4) With respect to those factors of quality which are rated by score points, each of the following requirements is met:

(i) None of the sample units falls more than one grade below the indicated grade because of any quality factor to which a limiting rule applies;

(ii) None of the sample units falls more than 4 score points below the minimum total score for the indicated grade; and

(iii) The number of sample units classed as deviants does not exceed the applicable acceptance number indicated in the sampling plans contained in § 260.61. A ''deviant,'' as used in this paragraph, means a sample unit that falls into the next grade below the indicated grade but does not score more than 4 points below the minimum total score for the indicated grade.

(5) If any of the provisions contained in paragraphs (b)(3) and (4) of this section are not met the grade is determined by considering such provisions in connection with succeedingly lower

grades until the grade of the lot, if assignable, is established.

§ 260.22 Order of inspection service.

Inspection service shall be performed, insofar as practicable, in the order in which applications therefor are made except that precedence may be given to any such applications which are made by the United States (including, but not being limited to, any instrumentality or agency thereof) and to any application for an appeal inspection.

§ 260.23 Postponing inspection service.

If the inspector determines that it is not possible to accurately ascertain the quality or condition of a processed product immediately after processing because the product has not reached equilibrium in color, or drained weight, or for any other substantial reason, he may postpone inspection service for such period as may be necessary.

§ 260.24 Financial interest of inspector.

No inspector shall inspect any processed product in which he is directly or indirectly financially interested.

§ 260.25 Forms of certificates.

Inspection certificates, certificates of sampling or loading, and other memoranda concerning inspection service shall be issued on forms approved by the Secretary.

§ 260.26 Issuance of certificates.

(a) An inspection certificate may be issued only by an inspector: *Provided,* That, another employee of the inspection service may sign any such certificate covering any processed product inspected by an inspector when given power of attorney by such inspector and authorized by the Secretary, to affix the inspector's signature to an inspection certificate which has been prepared in accordance with the facts set forth in the notes, made by the inspector, in connection with the inspection.

(b) A certificate of loading shall be issued and signed by the inspector or licensed sampler authorized to check the loading of a specific lot of processed products: *Provided,* That, another employee of the inspection service may sign such certificate of loading covering any processed product checkloaded by an inspector or licensed sampler when given power of attorney by such inspector or licensed sampler and authorized by the Secretary to affix the inspector's or licensed sampler's signature to a certificate of loading which has been prepared in accordance with the facts set forth in the notes made by the inspector or licensed sampler in connection with the checkloading of a specific lot of processed products.

§ 260.27 Issuance of corrected certificates.

A corrected inspection certificate may be issued by the inspector who issued the original certificate after distribution of a certificate if errors, such as incorrect dates, code marks, grade statements, lot or car numbers, container sizes, net or drained weights, quantities, or errors in any other pertinent information require the issuance of a corrected certificate. Whenever a corrected certificate is issued, such certificate shall supersede the inspection certificate which was issued in error and the superseded certificate shall become null and void after the issuance of the corrected certificate.

§ 260.28 Issuance of an inspection report in lieu of an inspection certificate.

A letter report in lieu of an inspection certificate may be issued by an inspector when such action appears to be more suitable than an inspection certificate: *Provided,* That, the issuance of such report is approved by the Secretary.

§ 260.29 Disposition of inspection certificates.

The original of any inspection certificate, issued under the regulations in this part, and not to exceed four copies thereof, if requested prior to issuance, shall be delivered or mailed promptly to the applicant, or person designated by the applicant. All other copies shall be filed in such manner as the Secretary may designate. Additional copies of any such certificates may be supplied to any interested party as provided in § 260.78.

§ 260.30 Report of inspection results prior to issuance of formal report.

Upon request of any interested party, the results of an inspection may be telegraphed or telephoned to him, or to any other person designated by him, at his expense.

APPEAL INSPECTION

§ 260.36 When appeal inspection may be requested.

An application for an appeal inspection may be made by any interested party who is dissatisfied with the results of an inspection as stated in an inspection certificate, if the lot of processed products can be positively identified by the inspection service as the lot from which officially drawn samples were previously inspected. Such application shall be made within thirty (30) days following the day on which the previous inspection was performed, except upon approval by the Secretary the time within which an application for appeal inspection may be made, may be extended.

§ 260.37 Where to file for an appeal inspection and information required.

(a) Application for an appeal inspection may be filed with:

(1) The inspector who issued the inspection certificate on which the appeal covering the processed product is requested; or

(2) The inspector in charge of the office of inspection at or nearest the place where the processed product is located.

(b) The application for appeal inspection shall state the location of the lot of processed products and the reasons for the appeal; and date and serial number of the certificate covering inspection of the processed product on which the appeal is requested, and such application may be accompanied by a copy of the previous inspection certificate and any other information that may facilitate inspection. Such application may be made orally (in person or by telephone), in writing, or by telegraph. If made orally, written confirmation shall be made promptly.

§ 260.38 When an application for an appeal inspection may be withdrawn.

An application for appeal inspection may be withdrawn by the applicant at any time before the appeal inspection is performed: *Provided,* That the applicant shall pay at the hourly rate prescribed in § 260.70, for the time incurred by the inspector in connection with such application, any travel expenses, telephone, telegraph, or other expenses which have been incurred by the inspection service in connection with such application.

[31 FR 16052, Dec. 15, 1966, as amended at 36 FR 18738, Sept. 21, 1971]

§ 260.39 When appeal inspection may be refused.

An application for an appeal inspection may be refused if:

(a) The reasons for the appeal inspection are frivolous or not substantial;

(b) The quality or condition of the processed product has undergone a material change since the inspection covering the processed product on which the appeal inspection is requested;

(c) The lot in question is not, or cannot be made accessible for the selection of officially drawn samples;

(d) The lot relative to which appeal inspection is requested cannot be positively identified by the inspector as the lot from which officially drawn samples were previously inspected; or

(e) There is noncompliance with the regulations in this part. Such applicant shall be notified promptly of the reason for such refusal.

§ 260.40 Who shall perform appeal inspection.

An appeal inspection shall be performed by an inspector or inspectors (other than the one from whose inspection the appeal is requested) authorized for this purpose by the Secretary and, whenever practical, such appeal inspection shall be conducted jointly by two such inspectors: *Provided,* That the inspector who made the inspection on which the appeal is requested may be authorized to draw the samples when another inspector or licensed sampler is not available in the area where the product is located.

§ 260.41 Appeal inspection certificate.

After an appeal inspection has been completed, an appeal inspection certificate shall be issued showing the results of such appeal inspection; and such certificate shall supersede the inspection certificate previously issued for the processed product involved. Each appeal inspection certificate shall clearly identify the number and date of the inspection certificate which it supersedes. The superseded certificate shall become null and void upon the issuance of the appeal inspection certificate and shall no longer represent the quality or condition of the processed product described therein. The inspector or inspectors issuing an appeal inspection certificate shall forward notice of such issuance to such persons as he considers necessary to prevent misuse of the superseded certificate if the original and all copies of such superseded certificate have not previously been delivered to the inspector or inspectors issuing the appeal inspection certificate. The provisions in the regulations in this part concerning forms of certificates, issuance of certificates, and disposition of certificates shall apply to appeal inspection certificates, except that copies of such appeal inspection certificates shall be furnished all interested parties who received copies of the superseded certificate.

LICENSING OF SAMPLERS AND INSPECTORS

§ 260.47 Who may become licensed sampler.

Any person deemed to have the necessary qualifications may be licensed as a licensed sampler to draw samples for the purpose of inspection under the regulations in this part. Such a license shall bear the printed signature of the Secretary, and shall be countersigned by an authorized employee of the Department. Licensed samplers shall have no authority to inspect processed products under the regulations in this part except as to identification and condition of the containers in a lot. A licensed sampler shall perform his duties pursuant to the regulations in this part as directed by the Director.

§ 260.48 Application to become a licensed sampler.

Application to become a licensed sampler shall be made to the Secretary on forms furnished for that purpose. Each such application shall be signed by the applicant in his own handwriting, and the information contained therein shall be certified by him to be true, complete, and correct to the best of his knowledge and belief, and the application shall contain or be accompanied by:

(a) A statement showing his present and previous occupations, together with names of all employers for whom he has worked, with periods of service, during the 10 years previous to the date of his application;

(b) A statement that, in his capacity as a licensed sampler, he will not draw samples from any lot of processed products with respect to which he or his employer is an interested party;

(c) A statement that he agrees to comply with all terms and conditions of the regulations in this part relating to duties of licensed samplers; and

(d) Such other information as may be requested.

§ 260.49 Inspectors.

Inspections will ordinarily be performed by employees under the Secretary who are employed as Federal Government employees for that purpose. However, any person employed under any joint Federal-State inspection service arrangement may be licensed, if otherwise qualified, by the Secretary to make inspections in accordance with this part on such processed products as may be specified in his license. Such license shall be issued only in a case where the Secretary is satisfied that the particular person is qualified to perform adequately the inspection service for which such person is to be licensed. Each such license shall bear the printed signature of the Secretary and shall be countersigned by an authorized employee of the Department. An inspector shall perform his duties pursuant to the regulations in this part as directed by the Director.

§ 260.50 Suspension or revocation of license of licensed sampler or licensed inspector.

Pending final action by the Secretary, the Director may, whenever he deems such action necessary, suspend the license of any licensed sampler, or licensed inspector, issued pursuant to the regulations in this part, by giving notice of such suspension to the respective licensee, accompanied by a statement of the reasons therefor. Within 7 days after the receipt of the aforesaid notice and statement of reasons by such licensee, he may file an appeal, in writing, with the Secretary supported by any argument or evidence that he may wish to offer as to why his license should not be suspended or revoked. After the expiration of the aforesaid 7 day period and consideration of such argument and evidence, the Secretary shall take such action as he deems appropriate with respect to such suspension or revocation.

§ 260.51 Surrender of license.

Upon termination of his services as a licensed sampler or licensed inspector, or suspension or revocation of his license, such licensee shall surrender his license immediately to the office of inspection serving the area in which he is located. These same provisions shall apply in a case of an expired license.

SAMPLING

§ 260.57 How samples are drawn by inspectors or licensed samplers.

An inspector or a licensed sampler shall select samples, upon request, from designated lots of processed products which are so placed as to permit thorough and proper sampling in accordance with the regulations in this part. Such person shall, unless otherwise directed by the Secretary, select sample units of such products at random, and from various locations in each lot in such manner and number, not inconsistent with the regulations in this part, as to secure a representative sample of the lot. Samples drawn for inspection shall be furnished by the applicant at no cost to the Department.

§ 260.58 Accessibility for sampling.

Each applicant shall cause the processed products for which inspection is requested to be made accessible for proper sampling. Failure to make any lot accessible for proper sampling shall be sufficient cause for postponing inspection service until such time as such lot is made accessible for proper sampling.

§ 260.59 How officially drawn samples are to be identified.

Officially drawn samples shall be marked by the inspector or licensed sampler so such samples can be properly identified for inspection.

§ 260.60 How samples are to be shipped.

Unless otherwise directed by the Secretary, samples which are to be shipped to any office of inspection shall be forwarded to the office of inspection serving the area in which the processed prodcuts from which the samples were drawn is located. Such samples shall be shipped in a manner to avoid, if possible, any material change in the quality or condition of the sample of the processed product. All transportation charges in connection with such shipments of samples shall be at the expense of the applicant and wherever practicable, such charges shall be prepaid by him.

§ 260.61 Sampling plans and procedures for determining lot compliance.

(a) Except as otherwise provided for in this section in connection with in-plant inspection and unless otherwise approved by the Secretary, samples shall be selected from each lot in the exact number of sample units indicated for the lot size in the applicable single sampling plan or, at the discretion of the inspection service, any comparable multiple sampling plan: *Provided,* That at the discretion of the inspection service the number of sample units selected may be increased to the exact number of sample units indicated for any one of the larger sample sizes provided for in the appropriate plans.

(b) Under the single sampling plans with respect to any specified requirement:

(1) If the number of deviants (as defined in connection with the specific requirements) in the sample does not exceed the acceptance number prescribed for the sample size the lot meets the requirement;

(2) If the number of deviants (as defined in connection with the specific requirement) in the sample exceeds the acceptance number prescribed for the sample size the lot fails the requirement.

(c) Under the multiple sampling plans inspection commences with the smallest sample size indicated under the appropriate plan and with respect to any specified requirement:

(1) If the number of deviants (as defined in connection with the specific requirement) in the sample being considered does not exceed the acceptance number prescribed for that sample size the lot meets the requirement;

(2) If the number of deviants (as defined in connection with the specific requirement) in the sample being considered equals or exceeds the rejection number prescribed for that sample size the lot fails the requirement; or

(3) If the number of deviants (as defined in connection with the specific requirement) in the sample being considered falls between the acceptance and rejection numbers of the plan, additional sample units are added to the sample so that the sample thus cumulated equals the next larger cumulative sample size in the plan. It may then be determined that the lot meets or fails the specific requirement by considering the cumulative sample and applying the procedures outlined in paragraphs (c)(1) and (2) of this section or by considering successively larger samples cumulated in the same manner until the lot meets or fails the specific requirement.

(d) If in the conduct of any type of inplant inspection the sample is examined before the lot size is known and the number of sample units exceeds the prescribed sample size for such lot but does not equal any of the prescribed larger sample sizes the lot may be deemed to meet or fail a specific requirement in accordance with the following procedure:

(1) If the number of deviants (as defined in connection with the specific requirement) in the nonprescribed sample does not exceed the acceptance number of the next smaller sample size the lot meets the requirements;

(2) If the number of deviants (as defined in connection with the specific requirement) in the nonprescribed sample equals the acceptance number prescribed for the next larger sample size additional sample units shall be selected to increase the sample to the next larger prescribed sample size;

(3) If the number of deviants (as defined in connection with the specific requirement) in the nonprescribed sample exceeds the acceptance number prescribed for the next larger sample size the lot fails the requirement.

(e) In the event that the lot compliance determination provisions of a standard or specification are based on the number of specified deviations instead of deviants the procedures set forth in this section may be applied by substituting the word ''deviation'' for the word ''deviant'' wherever it appears.

(f) Sampling plans referred to in this section are those contained in Tables I, II, III, IV, V, and VI which follow or any other plans which are applicable. For processed products not included in these tables, the minimum sample size shall be the exact number of sample units prescribed in the table, container group, and lot size that, as determined by the inspector, most closely resembles the product, type, container size and amount of product to be samples.

SINGLE SAMPLING PLANS AND ACCEPTANCE LEVELS

TABLE I—CANNED OR SIMILARLY PROCESSED FISHERY PRODUCTS, AND PRODUCTS THEREOF CONTAINING UNITS OF SUCH SIZE AND CHARACTER AS TO BE READILY SEPARABLE

Container size group	Lot size (number of containers)								
	Single sampling plans [1]								
GROUP 1									
Any type of container of less volume than that of a No. 300 size can (300×407)	3,600 or less	3,601–14,400	14,401–48,000	48,001–96,000	96,001–156,000	156,001–228,000	228,001–300,000	300,001–420,000	Over 420,000
GROUP 2									
Any type of container of a volume equal to or exceeding that of a No. 300 size can, but not exceeding that of a No. 3 cylinder size can (404×700)	2,400 or less	2,401–12,000	12,001–24,000	24,001–48,000	48,001–72,000	72,001–108,000	108,001–168,000	168,001–240,000	Over 240,000
GROUP 3									
Any type of container of a volume exceeding that of a No. 3 cylinder size can, but not exceeding that of a No. 12 size can (603×812)	1,200 or less	1,201–7,200	7,201–15,000	15,001–24,000	24,001–36,000	36,001–60,000	60,001–84,000	84,001–120,000	Over 120,000
GROUP 4									
Any type of container of a volume exceeding that of a No. 12 size can, but not exceeding that of a 5-gallon container	200 or less	201–800	801–1,600	1,601–2,400	2,401–3,600	3,601–8,000	8,001–16,000	16,001–28,000	Over 28,000
GROUP 5									
Any type of container of a volume exceeding that of a 5-gallon container	25 or less	26–80	81–200	201–400	401–800	801–1,200	1,201–2,000	2,001–3,200	Over 3,200

.

Sample size (number of sample units)[2]	3	6	13	21	29	38	48	60	72
Acceptance number	0	1	2	3	4	5	6	7	.....

[1] For extension of the single sample sizes beyond 72 sample units, refer to table V of this section; for multiple sampling plans comparable to the various single sampling plans refer to table VI of this section.

[2] The sample units for the various container size groups are as follows: Groups 1, 2, and 3—1 container and its entire contents. Groups 4 and 5—approximately 2 pounds of product. When determined by the inspector that a 2-pound sample unit is inadequate, a larger sample unit may be substituted.

TABLE II—FROZEN OR SIMILARLY PROCESSED FISHERY PRODUCTS, AND PRODUCTS THEREOF CONTAINING UNITS OF SUCH SIZE AND CHARACTER AS TO BE READILY SEPARABLE

Container size group	Lot size (number of containers)								
GROUP 1									
Any type of container of 1 pound or less net weight	2,400 or less	2,401–12,000	12,001–24,000	24,001–48,000	48,001–72,000	72,001–108,000	108,001–168,000	168,001–240,000	Over 240,000
GROUP 2									
Any type of container over 1 pound but not over 4 pounds net weight	1,800 or less	1,801–8,400	8,401–18,000	18,001–36,000	36,001–60,000	60,001–96,000	96,001–132,000	132,001–168,000	Over 168,000
GROUP 3									
Any type of container over 4 pounds but not over 10 pounds net weight	900 or less	901–3,600	3,601–10,800	10,801–18,000	18,001–36,000	36,001–60,000	60,001–84,000	84,001–120,000	Over 120,000
GROUP 4									
Any type of container over 10 pounds but not over 100 pounds net weight	200 or less	201–800	801–1,600	1,601–2,400	2,401–3,600	3,601–8,000	8,001–16,000	16,001–28,000	Over 28,000
GROUP 5									
Any type of container over 100 pounds net weight	25 or less	26–80	81–200	201–400	401–800	801–1,200	1,201–2,000	2,001–3,200	Over 3,200
	Single sampling plans[1]								
Sample size (number of sample units)[2]	3	6	13	21	29	38	48	60	72

Acceptance number	0	1	2	3	4	5	6	7	8

[1] For extension of the single sample sizes beyond 72 sample units, refer to table V of this section; for multiple sampling plans comparable to the various single sampling plans refer to table VI of this section.

[2] The sample units for the various container size groups are as follows: Groups 1, 2, and 3—1 container and its entire contents. Groups 4 and 5—approximately 3 pounds of product. When determined by the inspector that a 3-pound sample unit is inadequate, a larger sample unit or 1 or more containers and their entire contents may be substituted for 1 or more sample units of 3 pounds.

TABLE III—CANNED, FROZEN, OR OTHERWISE PROCESSED FISHERY AND RELATED PRODUCTS, AND PRODUCTS THEREOF OF A COMMINUTED, FLUID, OR HOMOGENEOUS STATE

Container size group [1]	Lot size (number of containers)								
GROUP 1									
Any type of container of 12 ounces or less	5,400 or less	5,401–21,600	21,601–62,400	62,401–112,000	112,001–174,000	174,001–240,000	240,001–360,000	360,001–480,000	Over 480,000
GROUP 2									
Any type of container over 12 ounces but not over 60 ounces	3,600 or less	3,601–14,400	14,401–48,000	48,001–96,000	96,001–156,000	156,001–228,000	228,001–300,000	300,001–420,000	Over 420,000
GROUP 3									
Any type of container over 60 ounces but not over 160 ounces	1,800 or less	1,801–8,400	8,401–18,000	18,001–60,000	36,001–60,000	60,001–96,000	96,001–132,000	132,001–168,000	Over 168,000
GROUP 4									
Any type of container over 160 ounces but not over 10 gallons or 100 pounds whichever is applicable	200 or less	201–800	801–1,600	1,601–3,200	3,201–8,000	8,001–16,000	16,001–24,000	24,001–32,000	Over 32,000
GROUP 5									
Any type of container over 10 gallons or 100 pounds whichever is applicable	25 or less	26–80	81–200	201–400	401–800	801–1,200	1,201–2,000	2,001–3,200	Over 3,200
Single sampling plans [2]									
Sample size (number of sample units) [3]	3	6	13	21	29	38	48	60	72
Acceptance number	0	1	2	3	4	5	6	7	8

[1] Ounces pertain to either fluid ounces of volume or avoirdupois ounces of net weight whichever is applicable for the product involved.

[2] For extension of the single sample sizes beyond 72 sample units, refer to table V of this section; for multiple sampling plans comparable to the various single sampling plans refer to table VI of this section.

[3] The sample units for the various container size groups are as follows: Groups 1, 2, and 3—1 container and its entire contents. A smaller sample unit may be substituted in group 3 at the inspector's discretion. Groups 4, 5, and 6—approximately 16 ounces of product. When determined by the inspector that a 16-ounce sample unit is inadequate, a larger sample unit may be substituted.

TABLE IV—DEHYDRATED FISHERY AND RELATED PRODUCTS

Container size group	Lot size (number of containers)								
GROUP 1									
Any type of container of 1 pound or less net weight	1,800 or less	1,801–8,400	8,401–18,000	18,001–36,000	36,001–60,000	60,001–96,000	96,001–132,000	132,001–168,000	Over 168,000
GROUP 2									
Any type of container over 1 pound but not over 6 pounds net weight	900 or less	901–3,600	3,601–10,800	10,801–18,000	18,001–36,000	36,001–60,000	60,001–84,000	84,001–120,000	Over 120,000
GROUP 3									
Any type of container over 6 pounds but not over 20 pounds net weight	200 or less	201–800	801–1,600	1,601–3,200	3,201–8,000	8,001–16,000	16,001–24,000	24,001–32,000	Over 32,000
GROUP 4									
Any type of container over 20 pounds but not over 100 pounds net weight	48 or less	49–400	401–1,200	1,201–2,000	2,001–2,800	2,801–6,000	6,001–9,600	9,601–15,000	Over 15,000
GROUP 5									
Any type of container over 100 pounds net weight	16 or less	17–80	81–200	201–400	401–800	801–1,200	1,201–2,000	2,001–3,200	Over 3,200
	Single sampling plans[1]								
Sample size (number of sample units)[2]	3	6	13	21	29	38	48	60	72
Acceptance number	0	1	2	3	4	5	6	7	8

[1] For extension of the single sample sizes beyond 72 sample units, refer to table V of this section; for multiple sampling plans comparable to the various single sampling plans refer to table VI of this section.

[2] The sample units for the various container size groups are as follows: Group 1—1 container and its entire contents. Groups 2, 3, 4, and 5—1 container and its entire contents or a smaller sample unit when determined by the inspector to be adequate.

TABLE V—SINGLE SAMPLING PLANS FOR USE IN INCREASING SAMPLE SIZE BEYOND 72 SAMPLE UNITS

Sample size, *n*	84	96	108	120	132	144	156	168	180	192	204	216	230	244	258	272	286	300	314	328	342	356	370	384	400

Acceptance numbers, *c*	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33

MULTIPLE SAMPLING PLANS [1]

TABLE VI—MULTIPLE SAMPLING PLANS COMPARABLE TO THE INDICATED SINGLE SAMPLING PLANS

Indicated single sampling plan:																									
Single sample size, *n*	6			13			21			29			38			48			60			72		
Acceptance numbers, *c*	1			2			3			4			5			6			7			8		
Cumulative sample sizes, n_c, and acceptance numbers, *c,* and rejection numbers, *r,* for multiple sampling.	n_c	*c*	*r*	n_c	*c*	*r*	n_c	*c*	*r*	n_c	*c*	*r*	n_c	*c*	*r*	n_c	*c*	*r*	n_c	*c*	*r*	n_c	*c*	*r*
	4	0	2	8	0	3	10	0	3	12	0	4	14	0	4	16	0	4	18	0	5	22	0	5
	6	0	2	10	0	3	14	1	4	16	0	4	20	0	5	24	1	5	28	1	6	32	1	7
	8	1	2	12	1	3	18	1	4	20	1	5	26	1	6	32	2	6	38	2	7	42	2	8
				14	2	3	22	2	5	24	2	5	32	2	6	40	3	8	48	3	8	52	3	9
							26	4	5	28	3	6	38	3	7	48	4	8	58	4	8	62	5	10
										32	3	6	44	6	7	56	7	8	68	8	9	72	6	10
										36	5	6										82	9	10

[1] These multiple sampling plans may be used in lieu of the single sampling plans listed at the heading of each column.

§ 260.62 Issuance of certificate of sampling.

Each inspector and each licensed sampler shall prepare and sign a certificate of sampling to cover the samples drawn by the respective person, except that an inspector who inspects the samples which he has drawn need not prepare a certificate of sampling. One copy of each certificate of sampling prepared shall be retained by the inspector or licensed sampler (as the case may be) and the original and all other copies thereof shall be disposed of in accordance with the instructions of the Secretary.

§ 260.63 Identification of lots sampled.

Each lot from which officially drawn samples are selected shall be marked in such manner as may be prescribed by the Secretary, if such lots do not otherwise possess suitable identification.

FEES AND CHARGES

§ 260.69 Payment fees and charges.

Fees and charges for any inspection service shall be paid by the interested party making the application for such service, in accordance with the applicable provisions of the regulations in this part, and, if so required by the person in charge of the office of inspection serving the area where the services are to be performed, an advance of funds prior to rendering inspection service in an amount suitable to the Secretary, or a surety bond suitable to the Secretary, may be required as a guarantee of payment for the services rendered. All fees and charges for any inspection service, performed pursuant to the regulations in this part shall be paid by check, draft, or money order made payable to the National Marine Fisheries Service. Such check, draft, or money order shall be remitted to the appropriate regional or area office serving the geographical area in which the services are performed, within ten (10) days from the date of billing, unless otherwise specified in a contract between the applicant and the Secretary, in which latter event the contract provisions shall apply.

[36 FR 21038, Nov. 3, 1971]

§ 260.70 Schedule of fees.

(a) Unless otherwise provided in a written agreement between the applicant and the Secretary, the fees to be charged and collected for any inspection service performed under the regulations in this part at the request of the United States, or any other agency or instrumentality thereof, will be published as a notice in the FEDERAL REGISTER and will be in accordance with § 260.81.

(b) Fees are reviewed annually to ascertain that the hourly fees charged are adequate to recover the costs of the services rendered.

(1) The TYPE I (Contract Inspection) hourly fee is determined by dividing the estimated annual costs by the estimated annual billable hours.

(2) The TYPE II (Lot Inspection) hourly fee is determined by adding a factor of 50 percent to the TYPE I fee, to cover additional costs (down-time, etc.) associated with conducting lot inspection services.

(3) The TYPE III (Miscellaneous and Consulting) hourly fee is determined by adding a factor of 25 percent to the TYPE I fee, to cover the additional costs (down-time, etc.) associated with conducting miscellaneous inspection services.

[48 FR 24901, June 3, 1983]

§ 260.71 [Reserved]

§ 260.72 Fees for inspection service performed under cooperative agreement.

The fees to be charged and collected for any inspection or similar service performed under cooperative agreement shall be those provided for by such agreement.

§ 260.73 Disposition of fees for inspections made under cooperative agreement.

Fees for inspection under a cooperative agreement with any State or person shall be disposed of in accordance with the terms of such agreement. Such portion of the fees collected under a cooperative agreement as may be due the United States shall be remitted in accordance with § 260.69.

§ 260.74 Fee for appeal inspection.

The fee to be charged for an appeal inspection shall be at the rates prescribed in this part for other inspection services: *Provided,* That, if the result of any appeal inspection made for any applicant, other than the United States or any agency or instrumentality thereof, discloses that a material error was made in the inspection on which the appeal is made, no inspection fee shall be assessed.

§ 260.76 [Reserved]

§ 260.77 Fees for score sheets.

If the applicant for inspection service requests score sheets showing in detail the inspection of each container or sample inspected and listed thereon, such score sheets may be furnished by the inspector in charge of the office of inspection serving the area where the inspection was performed; and such applicant shall be changed at the rate of $2.75 for each 12 sampled units, or fraction thereof, inspected and listed on such score sheets.

§ 260.78 Fees for additional copies of inspection certificates.

Additional copies of any inspection certificate other than those provided for in § 260.29, may be supplied to any interested party upon payment of a fee of $2.75 for each set of five (5) or fewer copies.

§ 260.79 Travel and other expenses.

Charges may be made to cover the cost of travel and other expenses incurred in connection with the performance of any inspection service, including appeal inspections: *Provided,* That, if charges for sampling or inspection are based on an hourly rate, an additional hourly charge may be made for travel time including time spent waiting for transportation as well as time spent traveling, but not to exceed 8 hours of travel time for any one person for any one day: *And provided further,* That, if travel is by common carrier, no hourly charge may be made for travel time outside the employee's official work hours.

§ 260.80 Charges for inspection service on a contract basis.

Irrespective of fees and charges prescribed in the foregoing sections, the Secretary may enter into a written memorandum of understanding or contract, whichever may be appropriate, with any administrative agency charged with the administration of a marketing order effective pursuant to the Agricultural Marketing Agreement Act of 1937, as revised (16 U.S.C. 661 et seq.) for the making of inspections pursuant to said agreement or order on such basis as will reimburse the National Marine Fisheries Service of the Department for the full cost of rendering such inspection service as may be determined by the Secretary. Likewise, the Secretary may enter into a written memorandum of understanding or contract, whichever may be appropriate, with an administrative agency charged with the administration of a similar program operated pursuant to the laws of any State.

[36 FR 21038, Nov. 3, 1971]

§ 260.81 Readjustment and increase in hourly rates of fees.

(a) When Federal Pay Act increases occur, the hourly rates for inspection fees will automatically be increased on the effective date of the pay act by an amount equal to the increase received by the average GS grade level of fishery product inspectors receiving such pay increases.

(b) The hourly rates of fees to be charged for inspection services will be subject to review and reevaluation for possible readjustment not less than every 3 years: *Provided,* That, the hourly rates of fees to be charged for inspection services will be immediately reevaluated as to need for readjustment with each Federal Pay Act increase.

[35 FR 15925, Oct. 9, 1970]

MISCELLANEOUS

§ 260.84 Policies and procedures.

The policies and procedures pertaining to any of the inspection services are contained within the NMFS Fishery Products Inspection Manual. The policies and procedures are available

from the Secretary to any interested party by writing to Document Approval and Supply Services Branch, Inspection Services Division, P.O. Drawer 1207, 3207 Frederic St., Pascagoula, MS 39568–1207.

[61 FR 9369, Mar. 8, 1996]

§ 260.86 Approved identification.

(a) *Grade marks:* The approved grade mark or identification may be used on containers, labels, or otherwise indicated for any processed product that:

(1) Has been packed under inspection as provided in this part to assure compliance with the requirements for wholesomeness established for the raw product and of sanitation established for the preparation and processing operations, and (2) has been certified by an inspector as meeting the requirements of such grade, quality or classification.

The grade marks approved for use shall be similar in form and design to the examples of Figures 1 to 5 of this section.

Shield using red, white, and blue background or other colors appropriate for label.

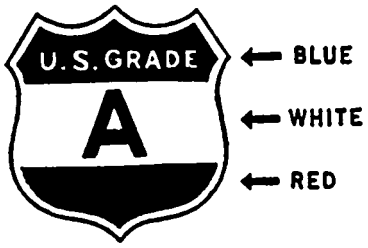

FIGURE 1.

Shield with plain background.

FIGURE 2.

U.S. GRADE A

FIGURE 3.

U.S.
GRADE
B

FIGURE 4.

U.S.
GRADE
C

FIGURE 5.

(b) *Inspection marks:* The approved inspection marks may be used on containers, labels, or otherwise indicated for any processed product that:

(1) Has been packed under inspection as provided in this part to assure compliance with the requirements for wholesomeness established for the raw product and of sanitation established

for the preparation and processing operations, and (2) has been certified by an inspector as meeting the requirements of such quality or grade classification as may be approved by the Secretary.

The inspection marks approved for use shall be similar in form and design to the examples in Figures 6, 7, and 8 of this section.

Statement enclosed within a circle.

FIGURE 6.

Statement without the use of the circle.

PACKED UNDER
FEDERAL
INSPECTION

U.S. DEPARTMENT
OF COMMERCE

FIGURE 7.

Statement without the use of the circle.

PACKED BY
_____
_____
UNDER FEDERAL INSPECTION
U.S. DEPT. OF COMMERCE

FIGURE 8.

(c) *Combined grade and inspection marks:* The grade marks set forth in paragraph (a) of this section, and the inspection marks, Figures 7 and 8, set forth in paragraph (b) of this section, may be combined into a consolidated grade and inspection mark for use on processed products that have been packed under inspection as provided in this part.

(d) *Products not eligible for approved identification:* Processed products which have not been packed under inspection as provided in this part shall not be identified by approved grade or inspection marks, but such products may be inspected on a lot inspection basis as provided in this part and identified by an authorized representative of the Department by stamping the shipping cases and inspection certificate(s) covering such lot(s) as appropriate, with marks similar in form and design to the examples in Figures 9 and 10 of this section.

FIGURE 9.

FIGURE 10.

(e) *Removal of labels bearing inspection marks:* At the time a lot of fishery products is found to be mislabeled and the labels on the packages are not removed within ten (10) consecutive calendar days, the following procedure shall be applicable:

(1) The processor, under the supervision of the inspector, shall clearly and conspicuously mark all master cases in the lot by means of a ''rejected by USDC Inspector'' stamp provided by the Department.

(2) The processor shall be held accountable to the Department for all mislabeled products until the products are properly labeled.

(3) Clearance for the release of the relabeled products shall be obtained by the processor from the inspector.

(f) Users of inspection services having an inventory of labels which bear official approved identification marks stating ''U.S. Department of the Interior'' or otherwise referencing the Interior Department, will be permitted to use such marks until December 31, 1971, except that upon written request the Director, National Marine Fisheries Service, may extend such period for the use of specific labels.

[36 FR 4609, Mar. 10, 1971]

§ 260.88 Political activity.

All inspectors and licensed samplers are forbidden, during the period of their respective appointments or licenses, to take an active part in political management or in political campaigns. Political activities in city, county, State, or national elections, whether primary or regular, or in behalf of any party or candidate, or any measure to be voted upon, are prohibited. This applies to all appointees or licensees, including, but not limited to, temporary and cooperative employees and employees on leave of absence with or without pay. Willful violation of this section will constitute grounds for dismissal in the case of appointees and revocation of licenses in the case of licensees.

§ 260.90 Compliance with other laws.

None of the requirements in the regulations in this part shall excuse failure to comply with any Federal, State, county, or municipal laws applicable to the operation of food processing establishments and to processed food products.

§ 260.91 Identification.

Each inspector and licensed sampler shall have in his possession at all times and present upon request, while on duty, the means of identification furnished by the Department to such person.

§ 260.93 Debarment and suspension.

(a) *Debarment.* Any person may be debarred from using or benefiting from the inspection service provided under the regulations of this subchapter or under the terms of any inspection contract, and such debarment may apply to one or more plants under his control, if such person engages in one or more of the following acts or activities:

(1) Misrepresenting, misstating, or withholding any material or relevant facts or information in conjunction with any application or request for an inspection contract, inspection service, inspection appeal, lot inspection, or other service provided for under the regulations of this subchapter.

(2) Using on a processed product any label which displays any official identification, official device, or official mark, when the label is not currently approved for use by the Director or his delegate.

(3) Using on a processed product any label which displays the words ''Packed Under Federal Inspection, U.S. Department of Commerce'', or which displays any official mark, official device, or official identification, or which displays a facsimile of the foregoing, when such product has not been inspected under the regulations of this subchapter.

(4) Making any statement or reference to the U.S. Grade of any processed product or any inspection service provided under the regulations of this subchapter on the label or in the advertising of any processed product, when such product has not been inspected under the regulations of this subchapter.

(5) Making, using, issuing or attempting to issue or use in conjunction with the sale, shipment, transfer or advertisement of a processed product any

certificate of loading, certificate of sampling, inspection certificate, official device, official identification, official mark, official document, or score sheet which has not been issued, approved, or authorized for use with such product by an inspector.

(6) Using any of the terms ''United States'', ''Officially graded'', ''Officially inspected'', ''Government inspected'', ''Federally inspected'', ''Officially sampled'', or words of similar import or meanings, or using any official device, official identification, or official mark on the label, on the shipping container, or in the advertising of any processed product, when such product has not been inspected under the regulations of this subchapter.

(7) Using, attempting to use, altering or reproducing any certificate, certificate form, design, insignia, mark, shield, device, or figure which simulates in whole or in part any official mark, official device, official identification, certificate of loading, certificate of sampling, inspection certificate or other official certificate issued pursuant to the regulations of this subchapter.

(8) Assaulting, harassing, interfering, obstructing or attempting to interfere or obstruct any inspector or sampler in the performance of his duties under the regulations of this subchapter.

(9) Violating any one or more of the terms of any inspection contract or the provisions of the regulations of this subchapter.

(10) Engaging in acts or activities which destroy or interfere with the purposes of the inspection program or which have the effect of undermining the integrity of the inspection program.

(b) *Temporary suspension.* (1) Whenever the Director has reasonable cause to believe that any person has engaged in any act or activity described in paragraph (a) of this section, and in such act or activity, in the judgment of the Director, would cause serious and irreparable injury to the inspection program and services provided under the regulations of this subchapter, the Director may, without a hearing, temporarily suspend, either before or after the institution of a debarment hearing, the inspection service provided under the regulations of this subchapter or under any inspection contract for one or more plants under the control of such person. Notice of suspension shall be served by registered or certified mail, return receipt requested, and the notice shall specifically state those acts or activities of such person which are the bases for the suspension. The suspension shall become effective five (5) days after receipt of the notice.

(2) Once a person has received a notice of a temporary suspension, a debarment hearing will be set for 30 days after the effective date of the suspension. Within 60 days after the completion of the debarment hearing, the Hearing Examiner shall determine, based upon evidence of record, whether the temporary suspension shall be continued or terminated. A temporary suspension shall be terminated by the Hearing Examiner if he determines that the acts or activities, which were the bases for the suspension, did not occur or will not cause serious and irreparable injury to the inspection program and services provided under the regulations of this subchapter. This determination of the Hearing Examiner on the continuation or termination of the temporary suspension shall be final and there shall be no appeal of this determination. The initial decision by the Hearing Examiner on the debarment shall be made in accordance with paragraph (b)(1), *Decisions,* of this section.

(3) After a debarment hearing has been instituted against any person by a suspension, such suspension will remain in effect until a final decision is rendered on the debarment in accordance with the regulations of this section or the temporary suspension is terminated by the Hearing Examiner.

(4) When a debarment hearing has been instituted against any person not under suspension, the Director may, in accordance with the regulations of this paragraph (b) temporarily suspend such person, and the suspension will remain in effect until a final decision on the debarment is rendered in accordance with the regulations of this section or the temporary suspension is terminated by the Hearing Examiner.

(c) *Hearing Examiner.* All hearing shall be held before a Hearing Examiner appointed by the Secretary or the Director.

(d) *Hearing.* If one or more of the acts or activities described in paragraph (a) of this section have occurred, the Director may institute a hearing to determine the length of time during which the person shall be debarred and those plants to which the debarment shall apply. No person may be debarred unless there is a hearing, as prescribed in this section, and it has been determined by the Hearing Examiner, based on evidence of record, that the one or more of the activities described in paragraph (a) of this section have occurred. Any debarment or suspension must be instituted within two (2) years of the time when such acts or activities described in paragraph (a) of this section have occurred.

(e) *Notice of hearing.* The Director shall notify such person of the debarment hearing by registered or certified mail, return receipt requested. The notice shall set forth the time and place of the hearing, the specific acts or activities which are the basis for the debarment hearing, the time period of debarment being sought, and those plants to which the debarment shall apply. Except for the debarment hearing provided for in paragraph (b) of this section the hearing will be set for a time not longer than 120 days after receipt of the notice of hearing.

(f) *Time and place of hearing.* The hearing shall be held at a time and place fixed by the Director: *Provided, however,* The Hearing Examiner may, upon a proper showing of inconvenience, change the time and place of the hearing. Motions for change of time or place of the hearing must be mailed to or served upon the Hearing Examiner no later than 10 days before the hearing.

(g) *Right to counsel.* In all proceedings under this section, all persons and the Department of Commerce shall have the right to be represented by counsel, in accordance with the rules and regulations set forth in title 43, Code of Federal Regulations, part 1.

(h) *Form, execution, and service of documents.* (1) All papers to be filed under the regulations in this section shall be clear and legible; and shall be dated, signed in ink, contain the docket description and title of the proceeding, if any, and the address of the signatory. Five copies of all papers are required to be filed. Documents filed shall be executed by:

(i) The person or persons filing same,

(ii) by an authorized officer thereof if it be a corporation or,

(iii) by an attorney or other person having authority with respect thereto.

(2) All documents, when filed, shall show that service has been made upon all parties to the proceeding. Such service shall be made by delivering one copy to each party in person or by mailing by first-class mail, properly addressed with postage prepaid. When a party has appeared by attorney or other representative, service on such attorney or other representative will be deemed service upon the party. The date of service of document shall be the day when the matter served is deposited in the U.S. mail, shown by the postmark thereon, or is delivered in person, as the case may be.

(3) A person is deemed to have appeared in a hearing by the filing with the Director a written notice of his appearance or his authority in writing to appear on behalf of one of the persons to the hearing.

(4) The original of every document filed under this section and required to be served upon all parties to a proceeding shall be accompanied by a certificate of service signed by the party making service, stating that such service has been made upon each party to the proceeding. Certificates of service may be in substantially the following form:

> I hereby certify that I have this day served the foregoing document upon all parties of record in this proceeding by: (1) Mailing postage prepaid, (2) delivering in person, a copy to each party.
>
> Dated at ——— this ——— day of ———, 19—
>
> Signature ———

(i) *Procedures and evidence.* (1) All parties to a hearing shall be entitled to introduce all relevant evidence on the issues as stated in the notice for hearing or as determined by the Hearing Examiner at the outset of or during the hearing.

(2) Technical rules of evidence shall not apply to hearings conducted pursuant to this section, but rules or principles designed to assure production of the most credible evidence available and to subject testimony to test by cross-examination shall be applied where reasonably necessary.

(j) *Duties of Hearing Examiner.* The Hearing Examiner shall have the authority and duty to:

(1) Take or cause depositions to be taken.

(2) Regulate the course of the hearings.

(3) Prescribe the order in which evidence shall be presented.

(4) Dispose of procedural requests or similar matters.

(5) Hear and initially rule upon all motions and petitions before him.

(6) Administer oaths and affirmations.

(7) Rule upon offers of proof and receive competent, relevant, material, reliable, and probative evidence.

(8) Control the admission of irrelevant, immaterial, incompetent, unreliable, repetitious, or cumulative evidence.

(9) Hear oral arguments if the Hearing Examiner determined such requirement is necessary.

(10) Fix the time for filing briefs, motions, and other documents to be filed in connection with hearings.

(11) Issue the initial decision and dispose of any other pertinent matters that normally and properly arise in the course of proceedings.

(12) Do all other things necessary for an orderly and impartial hearing.

(k) *The record.* (1) The Director will designate an official reporter for all hearings. The official transcript of testimony taken, together with any exhibits and briefs filed therewith, shall be filed with the Director. Transcripts of testimony will be available in any proceeding under the regulations of this section, at rates fixed by the contract between the United States of America and the reporter. If the reporter is an employee of the Department of Commerce, the rate will be fixed by the Director.

(2) The transcript of testimony and exhibits, together with all briefs, papers, and all rulings by the Hearing Examiner shall constitute the record. The initial decision will be predicated on the same record, as will be final decision.

(l) *Decisions.* (1) The Hearing Examiner shall render the initial decision in all debarment proceedings before him. The same Hearing Examiner who presides at the hearing shall render the initial decision except when such Examiner becomes unavailable to the Department of Commerce. In such case, another Hearing Examiner will be designated by the Secretary or Director to render the initial decision. Briefs, or other documents, to be submitted after the hearing must be received not later than twenty (20) days after the hearing, unless otherwise extended by the Hearing Examiner upon motion by a party. The initial decision shall be made within sixty (60) days after the receipt of all briefs. If no appeals from the initial decision is served upon the Director within ten (10) days of the date of the initial decision, it will become the final decision on the 20th day following the date of the initial decision. If an appeal is received, the appeal will be transmitted to the Secretary who will render the final decision after considering the record and the appeal.

(2) All initial and final decisions shall include a statement of findings and conclusions, as well as the reasons or bases therefore, upon the material issues presented. A copy of each decision shall be served on the parties to the proceeding, and furnished to interested persons upon request.

(3) It shall be the duty of the Hearing Examiner, and the Secretary where there is an appeal, to determine whether the person has engaged in one or more of the acts or activities described in paragraph (a) of this section, and, if there is a finding that the person has engaged in such acts or activities, the length of time the person shall be debarred, and the plants to which the debarment shall apply.

[31 FR 16052, Dec. 15, 1966, as amended at 36 FR 18738, Sept. 21, 1971]

REQUIREMENTS FOR PLANTS OPERATING UNDER CONTINUOUS INSPECTION ON A CONTRACT BASIS [1]

§ 260.96 Application for fishery products inspection service on a contract basis at official establishments.

Any person desiring to process and pack products in an establishment under fishery products inspection service on a contract basis, must receive approval of such buildings and facilities as an official establishment prior to the inauguration of such service. An application for inspection service to be rendered in an establishment shall be approved according to the following procedure:

(a) Initial survey: When application has been filed for inspection service as aforesaid, NMFS inspector(s) shall examine the buildings, premises, and facilities according to the requirements of the fishery products inspection service and shall specify any additional facilities required for the service.

(b) Final survey and establishment approval: Prior to the inauguration of the fishery products inspection service, a final survey of the buildings, premises, and facilities shall be made to verify that the buildings are constructed and facilities are in accordance with the approved drawings and the regulations in this part.

(c) Drawings and specifications of new construction or proposed alterations of existing official establishments shall be furnished to the Director in advance of actual construction for prior approval with regard to compliance with requirements for facilities.

[36 FR 21039, Nov. 3, 1971]

§ 260.97 Conditions for providing fishery products inspection service at official establishments.

(a) The determination as to the inspection effort required to adequately provide inspection service at any establishment will be made by NMFS. The man-hours required may vary at different official establishments due to factors such as, but not limited to, size and complexity of operations, volume and variety of products produced, and adequacy of control systems and cooperation. The inspection effort requirement may be reevaluated when the contracting party or NMFS deems there is sufficient change in production, equipment and change of quality control input to warrant reevaluation. Inspectors will not be available to perform any of employee or management duties, however, they will be available for consultation purposes. NMFS reserves the right to reassign inspectors as it deems necessary.

(b) NMFS shall not be held responsible:

(1) For damages occurring through any act of commission or omission on the part of its inspectors when engaged in performing services; or

(2) For production errors, such as processing temperatures, length of process, or misbranding of products; or

(3) For failure to supply enough inspection effort during any period of service.

(c) The contracting party will:

(1) Use only wholesome raw material which has been handled or stored under sanitary conditions and is suitable for processings; maintain the official establishment(s), designated on the contract in such sanitary condition and to employ such methods of handling raw materials for processing as may be necessary to conform to the sanitary requirements precribed or approved by NMFS;

(2) Adequately code each primary container and master case of products sold or otherwise distributed from a manufacturing, processing, packing, or repackaging activity to enable positive lot identification to facilitate, where necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use;

(3) Not permit any labels on which reference is made to Federal inspection, to be used on any product which is not packed under fishery products inspection service nor permit any labels on which reference is made to any U.S. Grade to be used on any product

[1] Compliance with the above requirements does not excuse failure to comply with all applicable sanitary rules and regulations of city, county, State, Federal, or other agencies having jursidiction over such establishments and operations.

which has not been officially certified as meeting the requirements of such grade; nor supply labels bearing reference to Federal inspection to another establishment unless the products to which such labels are to be applied have been packed under Federal inspection at an official establishment;

(4) Not affix any label on which reference is made to Federal inspection to any container of processed foods, produced in any designated official establishment, with respect to which the grade of such product is not certified because of adulteration due to the presence of contaminants in excess of limits established in accordance with the regulations or guidelines issued pursuant to the Food, Drug, and Cosmetic Act, as amended;

(5) Not, with respect to any product for which U.S. Grade Standards are in effect, affix any label on which reference is made to Federal inspection to any container of processed food which is substandard: *Provided,* That such label may be affixed to any container of such substandard quality product if such label bears a statement to indicate the substandard quality;

(6) Not, with respect to any product for which U.S. Grade Standard are not in effect, affix any label on which reference is made to the Federal inspection to containers of processed foods, except with the approval of NMFS;

(7) Furnish such reports of processing, packaging, grading, laboratory analyses, and output of products inspected, processed, and packaged at the designated official establish-ment(s) as may be requested by NMFS, subject to the approval of the Bureau of the Budget in accordance with the Federal Reports Act of 1942;

(8) Make available for use by inspectors, adequate office space in the designated official establishment(s) and furnish suitable desks, office equipment, and files for the proper care and storage of inspection records;

(9) Make laboratory facilities and necessary equipment available for the use of inspectors to inspect samples of processed foods and/or components thereof;

(10) Furnish and provide laundry service, as required by NMFS, for coats, trousers, smocks, and towels used by inspectors during performance of duty in official establishment(s);

(11) Furnish stenographic and clerical assistance as may be necessary in the typing of certificates and reports and the handling of official correspondence, as well as furnish the labor incident to the drawing and grading of samples and other work required to facilitate adequate inspection procedures whenever necessary;

(12) Submit to NMFS, three (3) copies of new product specifications in a manner prescribed by NMFS, and three (3) end-product samples for evaluation and/or laboratory analysis on all products for approval, for which U.S. Grade Standards are not available, when inspection is to be applied to such products. If requested of NMFS, such new specifications and end-product samples shall be considered confidential;

(13) Submit, as required by NMFS, for approval, proofs prior to printing and thereafter four (4) copies of any finished label which may or may not bear official identification marks, when such products are packed under Federal inspection on a contract basis;

(14) Not make deceptive, fraudulent, or unauthorized use in advertising, or otherwise, of the fishery products inspection service, the inspection certificates or reports issued, or the containers on which official identification marks are embossed or otherwise identified, in connection with the sale of any processed products;

(15) Submit to NMFS, four (4) copies of each label which may or may not bear official identification marks, when such labels are to be withdrawn from inspection or when approved labels are disapproved for further use under inspection;

(16) Notify NMFS in advance of the proposed use of any labels which require obliteration of any official identification marks, and all reference to the inspection service on approved labels which have been withdrawn or disapproved for use;

(17) Accord representatives of NMFS at all reasonable times free and immediate access to establishment(s) and official establishment(s) under applicant's control for the purpose of checking codes, coded products, coding devices, coding procedures, official identification marks obliteration, and use of withdrawn or disapproved labels.

(d) Termination of inspection services:

(1) The fishery products inspection service, including the issuance of inspection reports, shall be rendered from the date of the commencement specified in the contract and continue until suspended or terminated:

(i) By mutual consent;

(ii) by either party giving the other party sixty (60) days' written notice specifying the date of suspension or termination;

(iii) by one (1) day's written notice by NMFS in the event the applicant fails to honor any invoice within ten (10) days after date of receipt of such invoice covering the full costs of the inspection service provided, or in the event the applicant fails to maintain its designated plants in a sanitary condition or to use wholesome raw materials for processing as required by NMFS, or in the event the applicant fails to comply with any provisions of the regulations contained in this part;

(iv) by automatic termination in case of bankruptcy, closing out of business, or change in controlling ownership.

(2) In case the contracting party wishes to terminate the fishery products inspection service under the terms of paragraph (d)(1)(i) or (ii) of this section, either the service must be continued until all unused containers, labels, and advertising material on hand or in possession of his supplier bearing official identification marks, or reference to fishery products inspection service have been used, or said containers, labels, and advertising material must be destroyed, or official identification marks, and all other reference to the fishery products inspection service on said containers, labels, advertising material must be obliterated, or assurance satisfactory to NMFS must be furnished that such containers, labels, and advertising material will not be used in violation of any of the provisions of the regulations in the part.

(3) In case the fishery products inspection service is terminated for cause by NMFS under the terms of paragraph (d)(1)(iii) of this section, or in case of automatic termination under terms of paragraph (d)(1)(iv) of this section, the contracting party must destroy all unused containers, labels, and advertising material on hand bearing official identification marks, or reference to fishery products inspection service, or must obliterate official identification marks, and all reference to the fishery products inspection service on said containers, labels and advertising material.

After termination of the fishery products inspection service, NMFS may, at such time or times as it may determine to be necessary, during regular business hours, enter the establishment(s) or other facilities in order to ascertain that the containers, labels, and advertising material have been altered or disposed of in the manner provided herein, to the satisfaction of NMFS.

[36 FR 21039, Nov. 3, 1971]

§ 260.98 Premises.

The premises about an official establishment shall be free from conditions which may result in the contamination of food including, but not limited to, the following:

(a) Strong offensive odors;

(b) Improperly stored equipment, litter, waste, refuse, and uncut weeds or grass within the immediate vicinity of the buildings or structures that may constitute an attractant, breeding place, or harborage for rodents, insects, and other pests;

(c) Excessively dusty roads, yards, or parking lots that may constitute a source of contamination in areas where food is exposed;

(d) Inadequately drained areas that may contribute contamination to food products through seepage or foot-borne filth and by providing a breeding place for insects or micro-organisms;

If the grounds of an official establishment are bordered by grounds not under the official establishment operator's control of the kind described in

paragraphs (b) through (d) of this section, care must be exercised in the official establishment by inspection, extermination, or other means to effect exclusion of pests, dirt, and other filth that may be a source of food contamination.

[36 FR 21040, Nov. 3, 1971]

§ 260.99 Buildings and structures.

The buildings and structures shall be properly constructed and maintained in a sanitary condition, including, but not limited to the following requirements:

(a) *Lighting.* There shall be sufficient light (1) consistent with the use to which the particular portion of the building is devoted, and (2) to provide for efficient cleaning. Belts and tables on which picking, sorting, or trimming operations are carried on shall be provided with sufficient nonglaring light to insure adequacy of the respective operation. Light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation shall be of the safety type or otherwise protected to prevent food contamination in case of breakage.

(b) *Ventilation.* There shall be sufficient ventilation in each room and compartment thereof to prevent excessive condensation of moisture and to insure sanitary and suitable processing and operating conditions. If such ventilation does not prevent excessive condensation, the Director may require that suitable facilities be provided to prevent the condensate from coming in contact with equipment used in processing operations and with any ingredient used in the manufacture or production of a processed product.

(c) *Drains and gutters.* All drains and gutters shall be properly installed with approved traps and vents. The drainage and plumbing system must permit the quick runoff of all water from official establishment buildings, and surface water around buildings and on the premises; and all such water shall be disposed of in such a manner as to prevent a nuisance or health hazard. Tanks or other equipment whose drains are connected to the waste system must have such screens and vacuum breaking devices affixed so as to prevent the entrance of waste water, material, and the entrance of vermin to the processing tanks or equipment.

(d) *Water supply.* There shall be ample supply of both hot and cold water; and the water shall be of safe and sanitary quality with adequate facilities for its (1) distribution throughout buildings, and (2) protection against contamination and pollution.

Sea water of safe suitable and sanitary quality may be used in the processing of various fishery products when approved by NMFS prior to use.

(e) *Construction.* Roofs shall be weathertight. The walls, ceilings, partitions, posts, doors, and other parts of all buildings and structures shall be of such materials, construction, and finish as to permit their efficient and thorough cleaning. The floors shall be constructed of tile, cement, or other equally impervious material, shall have good surface drainage, and shall be free from openings or rough surfaces which would interfere with maintaining the floors in a clean condition.

(f) *Processing rooms.* Each room and each compartment in which any processed products are handled, processed, or stored (1) shall be so designed and constructed as to insure processing and operating conditions of a clean and orderly character; (2) shall be free from objectional odors and vapors; and (3) shall be maintained in a clean and sanitary condition.

(g) *Prevention of animals and insects in official establishment(s).* Dogs, cats, birds, and other animals (including, but not being limited to rodents and insects) shall be excluded from the rooms from which processed products are being prepared, handled, or stored and from any rooms from which ingredients (including, but not being limited to salt, sugar, spices, flour, batter, breading, and fishery products) are handled and stored. Screens, or other devices, adequate to prevent the passage of insects shall, where practical, be provided for all outside doors and openings. The use of chemical compounds such as cleaning agents, insecticides, bactericides, or rodent poisons shall not be permitted except under such precautions and restrictions as will prevent any possibility of their contamination of the processed product. The use of such compounds shall

be limited to those circumstances and conditions as approved by NMFS.

(h) *Inspector's office.* Furnished suitable and adequate office space, including, but not being limited to, light, heat, and janitor service shall be provided rent free in official establishments for use for official purposes by the inspector and NMFS representatives. The room or rooms designated for this purpose shall meet with the approval of NMFS and shall be conveniently located, properly ventilated, and provided with lockers or cabinets suitable for the protection and storage of inspection equipment and supplies and with facilities suitable for inspectors to change clothing.

(i) Adequate parking space, conveniently located, for private or official vehicles used in connection with providing inspection services shall be provided.

[36 FR 21040, Nov. 3, 1971]

§ 260.100 Facilities.

Each official establishment shall be equipped with adequate sanitary facilities and accommodations, including, but not being limited to, the following:

(a) Containers approved for use as containers for processed products shall not be used for any other purpose.

(b) No product or material not intended for human food or which creates an objectionable condition shall be processed, handled, or stored in any room, compartment, or place where any fishery product is manufactured, processed, handled, or stored.

(c) Suitable facilities for cleaning and sanitizing equipment (e.g., brooms, brushes, mops, clean cloths, hose, nozzles, soaps, detergent, sprayers) shall be provided at convenient locations throughout the plant.

[36 FR 21040, Nov. 3, 1971]

§ 260.101 Lavatory accommodations.

Modern lavatory accommodations, and properly located facilities for cleaning and sanitizing utensils and hands, shall be provided.

(a) Adequate lavatory and toilet accommodations, including, but not being limited to, running hot water (135° F. or more) and cold water, soap, and single service towels, shall be provided. Such accommodations shall be in or near toilet and locker rooms and also at such other places as may be essential to the cleanliness of all personnel handling products.

(b) Sufficient containers with covers shall be provided for used towels and other wastes.

(c) An adequate number of hand washing facilities serving areas where edible products are prepared shall be operated by other than hand-operated controls, or shall be of a continuous flow type which provides an adequate flow of water for washing hands.

(d) Durable signs shall be posted conspicuously in each toilet room and locker room directing employees to wash hands before returning to work.

(e) Toilet facilities shall be provided according to the following formula:

Number of persons	Toilet bowls required
1 to 15, inclusive	1
16 to 35, inclusive	2
36 to 55, inclusive	[1] 3
56 to 80, inclusive	[1] 4
For each additional 30 persons in excess of 80	[1] 1

[1] Urinals may be substituted for toilet bowls but only to the extent of one-third of the total number of bowls required.

All toilet equipment shall be kept operative, in good repair, and in a sanitary condition.

[36 FR 21041, Nov. 3, 1971]

§ 260.102 Equipment.

All equipment used for receiving, washing, segregating, picking, processing, packaging, or storing any processed products or any ingredients used in the manufacture or production thereof, shall be of such design, material, and construction as will:

(a) Enable the examination, segregation, preparation, packaging, and other processing operations applicable to processed products, in an efficient, clean, and sanitary manner, and

(b) Permit easy access to all parts to insure thorough cleaning and effective bactericidal treatment. Insofar as is practicable, all such equipment shall be made of smooth impermeable corrosion-resistant material that will not adversely affect the processed product by chemical action or physical contact. Such equipment shall be kept in good repair and sanitary condition. Such

equipment shall be cleaned and sanitized at a frequency as is necessary or required in accordance with Good Manufacturing Practice Regulations, 21 CFR part 128.

[36 FR 21041, Nov. 3, 1971]

§ 260.103 Operations and operating procedures shall be in accordance with an effective sanitation program.

(a) All operators in the receiving transporting, holdings, segregating, preparing, processing, packaging, and storing of processed products and ingredients, used as aforesaid, shall be strictly in accord with clean and sanitary methods and shall be conducted as rapidly as possible and at temperatures that will inhibit and retard the growth of bacterial and other micro-organisms and prevent any deterioration or contamination of such processed products or ingredients thereof. Mechanical adjustments or practices which may cause contamination of foods by oil, dust, paint, scale, fumes, grinding materials, decomposed food, filth, chemicals, or other foreign materials shall not be conducted during any manufacturing or processing operation.

(b) All processed products, raw materials, ingredients, and components thereof shall be subject to inspection during each manufacturing or processing operation. To assure a safe, wholesome finished product, changes in processing methods and procedures as may be required by the Director shall be effectuated as soon as practicable. All processed products which are not manufactured or prepared in accordance with the requirements contained in § 260.96 to § 260.104 or are unwholesome or otherwise not fit for human food shall be removed and segregated prior to any further processing operation.

(c) Official establishments operating under Federal inspection should have an effective quality control program as appropriate for the nature of the products and processing operations.

(d) All ingredients used in the manufacture or processing of any processed product shall be wholesome and fit for human food.

(e) The methods and procedures employed in the receiving, segregating, handling, transporting, and processing of ingredients in official estab lishment(s) shall be adequate to result in a satisfactory processed product. Such methods and procedures include, but are not limited to, the following requirements:

(1) Containers, utensils, pans, and buckets used for the storage or transporting of partially processed food ingredients shall not be nested unless rewashed and sanitized before each use;

(2) Containers which are used for holding partially processed food ingredients shall not be stacked in such manner as to permit contamination of the partially processed food ingredients;

(3) Packages or containers for processed products shall be clean when being filled with such products; and all reasonable precautions shall be taken to avoid soiling or contaminating the surface of any package or container liner which is, or will be, in direct contact with such products.

(f) Retention tags: (1) Any equipment such as, but not limited to, conveyors, tillers, sorters, choppers, and containers which fail to meet appropriate and adequate sanitation requirements will be identified by the inspector in an appropriate and conspicuous manner with the word ''RETAINED.'' Following such identification, the equipment shall not be used until the discrepancy has been resolved, the equipment reinspected and approved by the inspector and the ''RETAINED'' identification removed by the inspector.

(2) Lot(s) of processed products that may be considered to be mislabeled and/or unwholesome by reason of contaminants or which may otherwise be in such condition as to require further evaluation or testing to determine that the product properly labeled and/or wholesome will be identified by the inspector in an appropriate and conspicuous manner with the word ''RETAINED.'' Such lot(s) of product shall be held for reinspection or testing. Final disposition of the lot(s) shall be determined by NMFS and the removal of the ''RETAINED'' identification shall be performed by the inspector.

[36 FR 21041, Nov. 3, 1971]

§ 260.104 Personnel.

The establishment management shall be responsible for taking all precautions to assure the following:

(a) *Disease control.* No person affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds, or other abnormal sources of microbiological contamination, shall work in a food plant in any capacity in which there is a reasonable possibility of food ingredients becoming contaminated by such person, or of disease being transmitted by such person to other individuals.

(b) *Cleanliness.* All persons, while working in direct contact with food preparation, food ingredients, or surfaces coming into contact therewith shall:

(1) Wear clean outer garments, maintain a high degree of personal cleanliness, and conform to hygenic practices while on duty, to the extent necessary to prevent contamination of food products.

(2) Wash and sanitize their hands thoroughly to prevent contamination by undesirable microorganisms before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(3) Remove all insecure jewelry and, when food is being manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized.

(4) If gloves are used in food handling, maintain them in an intact, clean, and sanitary condition. Such gloves shall be of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.

(5) Wear hair nets, caps, masks, or other effective hair restraints. Other persons that may incidentally enter the processing areas shall comply with this requirement.

(6) Not store clothing or other personal belongings, eat food, drink beverages, chew gum, or use tobacco in any form in areas where food or food ingredients are exposed or in areas used for washing equipment or utensils.

(7) Take any other necessary precautions to prevent contamination of foods with microorganisms or foreign substances including, but not limited to perspiration, hair, cosmetics, tobacco, chemicals, and medicants.

(c) *Education and training.* Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean wholesome food. Food handlers and supervisors should receive appropriate training in proper food-handling techniques and food-protection principles and should be cognizant of the danger of poor personal hygiene and unsanitary practices, and other vectors of contamination.

[36 FR 21041, Nov. 3, 1971]

LABELING REQUIREMENTS

§§ 260.200–260.201 [Reserved]

PART 261—UNITED STATES STANDARDS FOR GRADES

Sec.

AUTHORITY: 7 U.S.C. 1621–1630.

SOURCE: 61 FR 9369, Mar. 8, 1996, unless otherwise noted.

§ 261.101 Standard description.

A U.S. Standard for Grades authorized under this part is a standard for a fish or fishery product that has been developed and adopted by the voluntary seafood inspection program pursuant to the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 *et seq.*) and other authorities delegated to the U.S. Department of Commerce.

§ 261.102 Publication and removal of U.S. Grade Standards.

(a) The voluntary U.S. Standards for Grades adopted pursuant to this part shall be issued as Program policies and contained within the NMFS Fishery Products Inspection Manual. Compliance with voluntary standards issued as Program policies within the manual shall satisfy the requirements of this

NOAA HACCP

Quality Management Program

(HACCP QMP)

Program Requirements

(Rev-January 1, 2000)

National Marine Fisheries Service

Seafood Inspection Program
1315 East-West Highway
Silver Spring, Maryland 20910

NOAA HACCP Quality Management Program

Authority

Authority for the Seafood Inspection Program to provide this HACCP Quality Management Program can be found in 50 CFR 260.103

Introduction

HACCP (Hazard Analysis Critical Control Point) is a non-traditional, non-continuous inspection technique recommended by the National Academy of Sciences as a more scientific, analytical, and economical approach than that provided by traditional inspection and quality control methods. HACCP, which focuses on problem prevention and problem solving, relies heavily on proper monitoring and record keeping by the industry. One of the primary economic benefits of HACCP is that it provides for reduced destructive sampling of the finished product as compared to the end-product sampling required under traditional inspection systems. The application of HACCP principles to seafood inspection has been adopted by several countries, including Canada, Iceland, and the European Union, and is becoming more broadly recognized by the international community as a mechanism to apply uniform inspection procedures.

HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product. For successful implementation of a HACCP plan, management must be strongly committed to the HACCP concept. A firm commitment to HACCP by top management provides company employees with a sense of the importance of producing safe food.

In July 1992, NOAA Fisheries (NOAA) published a Federal Register notice announcing the availability of a new seafood inspection program based on Hazard Analysis Critical Control Point (HACCP) principles. This program is in addition to the Integrated Quality Assurance (IQA) Program that also uses HACCP principles. However, the IQA program, having unique methods for the inspection and grading of products, will continue as an option for applicants to the program.

The guidelines for the HACCP Quality Management Program have been compiled to inform interested parties that the NOAA is offering an alternative inspection program in addition to what is presently available. Participation in one program over the other is a decision, which must be made by the company's management. Under the Quality Management Program, the company takes on the responsibility of documenting and implementing a quality system. NOAA will then ensure that the quality system in place is adequate to control the critical functions by regular inspections of the system, known as audits. These audits will evaluate the quality system by examining product, processes, and records.

This document includes sections, which explain the specifications or requirements of the QMP program for documenting a quality system that will meet NOAA requirements. The document is also a guide manual for use by interested parties in developing their own quality manual. The HACCP Quality Management Program will allow participants an opportunity to apply their existing quality systems more efficiently, receive the management benefits of producing safe, wholesome, and properly labeled products more consistently and obtain the marketing benefits of using marks associated with the program.

In summary, the HACCP-based service is consistent with global activities to harmonize inspection protocols. In addition, NOAA believes that the service will enhance the safety, wholesomeness, economic integrity, and quality of seafood available to consumers, as well as improve seafood industry quality assurance and regulatory oversight.

Scope

NOAA policy is to encourage and assist interested parties in the development and implementation of HACCP-based quality management systems to facilitate consistent distribution of safe, wholesome, and properly labeled fishery products of desired uniform quality. The development and implementation of HACCP-quality management systems is optional. However, their use should result in more efficient use of NOAA resources to inspect, grade, and certify fishery products. This document is designed to provide guidance for the development, implementation, and operation of HACCP-quality management systems, which will meet NOAA approval.

Definitions

1. **Auditee:** The organization being audited.
2. **Auditor:** A person qualified to perform audits.
3. **Contamination:** The occurrence of a contaminant in fish due to microbial pathogens, chemicals, foreign bodies, spoilage, objectionable taints, unwanted or diseased matter, which may compromise fish safety or suitability.
4. **Control measure (preventive measure):** Action performed to eliminate a hazard or reduce it to an acceptable level. For the purposes of this guide a control measure is also applied to a defect.
5. **Control Point:** Any step in a process whereby biological, chemical, or physical factors may be controlled.
6. **Corrective Actions:** An action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence.
7. **Critical Control Point (CCP):** A point, step, or procedure in a food process at which control can be applied, and a food hazard can as a result be prevented, eliminated, or reduced to acceptable levels.
8. **Critical Deficiency:** A hazardous deviation from plan requirements such that maintenance of the safety, wholesomeness, and economic integrity is absent; will result in unsafe, unwholesome, or misbranded product.
9. **Critical Limit:** The maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point, or defect action point, to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.
10. **Decision Tree:** A sequence of questions applied to each process step with an identified hazard to identify which process steps are CCPs. For the purpose of this Program this also applies to a Defect Action Point.
11. **Decomposition:** A persistent and distinct objectionable odor or flavor including texture breakdown caused by the deterioration of fish.
12. **Defect:** A condition found in a product which fails to meet essential quality, composition and/or labeling provisions of the appropriate product standards or specifications.
13. **Defect Action Point (DAP):** A point, step or procedure at which control can be applied and a defect can be prevented, eliminated or reduced to acceptable level, or a fraud risk eliminated.
14. **Food Safety Hazard:** Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.
15. **HACCP Plan:** A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety and control of defects which are significant for essential quality, composition, and/or labeling provisions in the segment of the food chain under consideration.
16. **Hazard:** A chance for, or the risk of, a biological, chemical, physical, or economic property in a food product that could violate established program criteria or cause the consumer distress or illness.
17. **Hazard analysis:** The process of collecting and evaluating information on hazards and conditions leading to their presence to decide

which are significant for food safety and therefore should be addressed in the HACCP plan.

18. **High risk products:** Seafood that may pose a significant danger to the health of the public when prepared for consumption by conventional or traditional means. For example, ready-to-eat; heat and/or brown and serve products; products which may contain a microbial pathogen, biotoxin, or physical or chemical contaminant which may pose an unacceptable health risk at the time of consumption.
18. **Low risk products:** Seafood that poses no significant risk to the health of the public when prepared for consumption by conventional or traditional means.
19. **Major Deficiency:** A significant deviation from plan requirements, such that maintenance of safety, wholesomeness, or economic integrity is inhibited.
20. **Minor Deficiency:** A failure of the part of the HACCP-based system relative to facility sanitation which is not likely to reduce materially the facility's ability to meet acceptable sanitation requirements.
21. **Monitoring Procedures:** Scheduled testing and/or observations recorded by the firm to report the findings at each CCP or DAP.
22. **NUOCA (Notice of Unusual Occurrence and Corrective Action):** The record that outlines the incident and the corresponding corrective action implemented by the facility.
23. **Objective Evidence:** Information, which can be proved true, based on facts, obtained through observation, measurement, test, or other means.
24. **Prerequisite Program:** Procedures, including Good Manufacturing Practices that address operational conditions providing the foundation for the HACCP system.
25. **Preventive Measure(s) (control measure):** Physical, chemical, or other factors that can be used to control an identified food safety hazard. For the purposes of this program, this also applies to a DAP.
26. **Process:** One or more actions or operations to harvest, produce, store, handle, distribute, or sell a product or group of similar products.
27. **Quality:** Totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs. The inherent properties of any processed product which determine the relative degree of excellence of such product, and includes the effects of preparation and processing, and may or may not include the effects of packing media, or added ingredients.
28. **Quality Audit:** A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.
29. **Record:** A document that furnishes objective evidence of activities performed or results achieved.
30. **Serious Deficiency:** A severe deviation from plan requirements such that maintenance of safety, wholesomeness, and economic integrity is prevented; and, if the situation is allowed to continue, may result in unsafe, unwholesome, or misbranded product.
31. **Severity:** The seriousness of the effect(s) of a hazard or defect.
32. **Specification:** A document stating requirements. A detailed document describing the materials, dimensions, and workmanship requirements of a product.
33. **Systems Audit:** On-site NOAA evaluation of the firm's effectiveness in following the plan after validation.
34. **Validation:** That element of verification focused on collecting and evaluating scientific and technical information to determine if the Quality Management Plan, when properly implemented, will effectively control the hazards and defects.
35. **Verification:** Those activities performed by the firm, other than monitoring, that determine the validity of the Quality Management Plan and that the system is operating according to the plan.

Applying to Enter the Program

Firms who wish to participate in the Program may apply orally or in writing to the appropriate Regional Inspection Branch. If application is made orally, it must be confirmed promptly in writing. The Regional Inspection Branch will provide the applicant with all necessary materials to inform them of the program and its requirements. This material will also include the requirements and any policies necessary for development and submission of a Quality Management Plan. The firm develops its Quality Management Plan and submits it for review according to the plan review procedures described further in this document.

NOTE: Firms who wish to have a more in-depth presentation of the Program and its requirements may request a meeting of all interested parties. This may incur a cost and should be discussed with the Regional Inspection Branch.

Education and Training

The success of a HACCP system depends on educating and training management and employees in the importance of their role in producing safe foods. This should also include information concerning the control of food borne hazards related to all stages of the food chain. It is important to recognize that employees must first understand what HACCP and quality management is and then learn the skills necessary to make it function properly. Specific training activities should include working instructions and procedures that outline the tasks of employees monitoring each CCP or DAP.

Management must provide adequate time for thorough education and training. Personnel must be given the materials and equipment necessary to perform these tasks. Effective training is an important prerequisite to successful implementation of a HACCP or quality plan. ***Each facility must employ a NOAA-certified person knowledgeable in the program's principles to be present during all processing times. The certification must be kept on file and available to NOAA at all times.***

NOTE: Retail establishments of significant size do not require the certification of an individual at each store or facility location. However, they must have demonstrated sufficient control of the training of all pertinent individuals and have a sufficient number of management personnel trained and certified in their system to maintain proper control of the concepts and the HACCP plan.

Plan Review and Desk Audit

Each applicant must submit a QMP plan in accordance with this document. At the request of the firm, NOAA will provide consultation toward the development of the HACCP Quality Management Program plan on a fee basis.

Plans are submitted to the servicing Regional Inspection Branch for desk review. Reviews of the plan may require requests for changes, clarifications, deletions, etc., from the firm. The servicing region will work with the firm to finalize the development of the QMP Plan. A written review is sent to the firm indicating what changes, if any, are necessary prior to scheduling the site visit. All work of the assigned CSO and the Regional Inspection Branch is performed on a fee basis at established rates.

Label Review Procedures

All applicable labels must be approved prior to use in accordance with Part I, Chapter 3, Section 5 of NOAA Handbook 25, Inspection Manual.

System Assessment, Site Visit, and Plan Approval

The firm should begin following their plan as soon as possible. The firm must adhere to the plan's provisions and keep all records associated with the approved QMP plan for at least five (5) consecutive production days. The firm will contact the Regional Inspection Branch as soon as they believe the approved plan is functioning successfully and when they have records covering the minimum production days. The Regional Inspection Branch will schedule a site visit with the firm. The firm must verify through

end-product examination that the process controls result in product which complies to all regulations and applicable quality standards or specifications. If documentation has not been previously provided, the firm must collect data prior to the site visit which will be sufficient to demonstrate this relationship. Firms attempting to document this relationship must collect data on not less than 20 percent of their lots using sampling plans comparable in statistical confidence to those in 50 CFR Part 260, with at least one lot representing each product form. The inspection records must be available to NOAA personnel upon request. Although not required, NOAA recommends that the firm submit end-item verification records with their QMP Plan. This will allow the firm to test their controls, provide plan reviewers more information, and possibly reduce the time and cost of the site visit.

The audit performed on site will determine whether all of the hazards/defects and CCPs/DAPs have been identified, the quality management plan is being followed and monitored by the firm, and is effectively controlling the identified hazards/defects. The site visit will be conducted on a fee basis by a team of personnel assigned based upon the needs of the audit and the expertise available. The number and structure of the team will be determined by the size and complexity of the firm's process and nature of hazards associated with the products covered under the QMP Plan. The audit will include conducting document and record reviews, evaluating sanitation and in-process observations and product verification. All reviews will be performed using accepted auditing practices based on the current standards of ISO 10011. Conducting a combination of statistical reviews of records and finished product sample inspections will complete product verifications. At least one lot for each product form will be verified by inspecting samples of finished product. NOAA inspection personnel may, for cause, sample and verify product in excess of this guideline. Firms will be evaluated using the QMP System Evaluation Criteria. If the firm is determined to be acceptable it will qualify as a participant in the program and may finalize a contract for services with NOAA. If the audit at the firm is favorable, all products under review during the audit, including the previous five (5) production days, are eligible to bear the appropriate official marks or advertising claim.

Note for Vessels: Due to logistical factors, only one NOAA Consumer Safety Officer will perform the site visit. The NOAA Consumer Safety Officer will accompany the vessel, if determined necessary, for an appropriate time period during a fishing season, performing the background checks of critical control points and auditing the plan at one time. The officer may assist the quality assurance/management group on board the vessel in any alterations to make to their QMP Plan to work toward plan approval and a successful audit. Once the QMP plan is approved, the officer is taken off the vessel as soon as is practicable. These procedural accommodations are made in recognition of possible space restrictions and to reduce the numbers of transfers at sea.

QMP Plan Changes

After the QMP plan has been approved, modifications may be made under the following conditions. The firm must notify the servicing Regional Inspection Branch, in writing (Faxes are acceptable), of any modifications in their QMP plan before implementing the changes. However, any changes to address a health or safety issue may be made without prior approval, but must be documented in a corrective action plan. The Regional Inspection Branch must be notified of these immediate changes within one working day.

As the QMP Plan outlines the basic foundation and policies of the firm's quality program, changes to the plan must be approved in advance with Program management. However, the specific work procedures may change as necessary without prior approval, as long as they meet the NOAA Program Quality System Standard found at the end of this document. Prior to signing the contract, it will be determined

what of the firm's document requires pre-approval.

Systems Audits

Only with a valid contract and continued demonstrated compliance with all applicable laws and regulations and policies may 1) the firm be eligible to use official marks or other related statements and 2) firm-collected data be used by NOAA towards issuing official certification of the firm's products or facility compliance. After the firm's QMP Plan is approved, NOAA will conduct Systems Audits at a frequency listed below to determine the firm's continued adherence to their QMP Plan.

Table 1

	Systems Audit Target Frequencies			Deficiencies			
Facility Rating	**Processors**	**Retail**	**Vessels**	**Minor**	**Major**	**Serious**	**Critical**
Reduced	Once every calendar quarter	Once every six months	Once every fourth trip	**0-6**	**0-5**	**1**	**0**
Normal	Once every month	Once every calendar quarter	Once every other trip*	**≥7**	**6-10**	**2-4**	**0**
Tightened	Daily Until Corrected	Daily Until Corrected	Daily Until Corrected	**NA**	**≥11**	**≥5**	**≥1**
Requirements to be Audited at a Reduced Frequency	Three consecutive audits at Reduced Deficiency criteria	Three consecutive audits at Reduced Deficiency criteria	Two consecutive audits at Reduced Deficiency criteria				

* An audit of a trip will consist of ten percent of the total trip days. If for example the trip is 30 days, the audit will consist of three days during the trip.

Vessels

Firms must provide the appropriate NOAA Regional Inspection Branch with their tentative season schedules and off-loading schedules and sites as soon as they are known. Firms must give the servicing Regional Inspection Branch notice prior to each port arrival, providing sufficient time for auditors to verify and audit the vessel when required. Failure to do so could result in the removal of the vessel from the Program. Vessels will be visited once every other trip, with at least one visit per year.

A visit will be composed of a maximum of ten (10) percent of the scheduled fishing days for the trip in question. For example, if a trip is scheduled to last 30 days, the Systems Audit will be performed over approximately three days. Additional days may be necessary if the Consumer Safety Officer has encountered a problem during the audit. Audits may not require the auditor to be on board during fishing, but will require the auditor to be present during off-loading.

NOTE: Samples of finished product may be pulled while the NOAA Consumer Safety Officer is on board or at dockside. If samples are pulled while on board, they will be evaluated immediately for compliance.

Processing Establishments

NOAA will conduct unannounced Systems Audits to determine the firm's continued adherence to their plan. Facilities will be visited at least once every month.

Retail and Food Service Establishments

NOAA will conduct unannounced Systems Audits at the frequencies outlined in Table 1 to determine the firm's continued adherence to their plan. Facilities will be visited at least once every three months.

NOTE: NOAA is interested in providing this program with a minimum possible burden to retail participants. Record keeping should not be so grand as to cause undue hardship on the retailer. Records should be of a precision only to show what products were received by what supplier on a particular day.

Procedures for Retail and Food Service Operations with Multiple Outlets and with an Established Quality Assurance Program

Firms which operate a chain of stores may have the stores under the program sampled as outlined in the chart below (provided they have an established approved Quality Assurance System).

Table 2

	Stores to Sample Quarterly		
Number of Facilities	**Reduced**	**Normal**	**Tightened**
2 - 4	1	2	ALL
5 - 8	3	4	5
9 - 12	4	6	8
13 - 16	6	8	10
17 - 20	8	10	13
21 - 30	9	13	18
31 - 40	10	15	21
41 - 70	10	18	25
71 - 100	10	19	30
101 or more	10	20	35

In addition, the following criteria apply:

1. All firms will enter the Program at the Tightened level of sampling. After two successive audits at this level, the firm will move to the Normal level of sampling. After two successive audits at the Normal level, the firm will move to the Reduced level of sampling.
2. No stores in the sample may be considered unreliable. If a store in the sample is deemed unreliable (Five Serious deficiencies or One Critical deficiency), the Firm's Quality Assurance System is suspect. NOAA will then perform an audit on the Quality Assurance System of the firm for the next thirty days. This audit will include the sampling of additional stores. During this 30 day period, the stores may continue to use all advertisement claims.
3. If after this audit the Quality Assurance System is deemed to be under control, the firm will be sampled at the Tightened level and the system begins again as described above.
4. If the Quality Assurance System is deemed to not be performing as designed, Regional management and the Quality Team will evaluate the firm's entire program and suggest the necessary changes to continue in the Program. This evaluation could include each store being audited and/or removed from the Program or may result in a permanent or temporary removal of the firm from the Program.
5. During this thirty day period the stores may continue to use all advertisement claims.
6. If the sample of stores does not meet the above requirements, then each store in the chain must be audited on its own until such time as the Quality Assurance System has been re-approved.

Tightened Frequency Audit Procedures

A firm at the tightened frequency has demonstrated difficulties in administering their QMP Plan and has rated the facility as unreliable. If a Consumer Safety Officer rates a facility unreliable, he/she will rate the facility and immediately contact his/her Supervisor. The decision to rate a facility unreliable will be made prior to the Consumer Safety Officer performing the exit interview. Once the rating is confirmed, the Chief Quality Officer of the Seafood Inspection Program is to be informed and provided with all documentation, including but not limited to: Final Audit Report, scoresheets, supporting documentation, etc. Facilities who are rated unreliable have a period of thirty days

to remove the unreliable status. Failure to do so will result in the facility's removal from the NOAA HACCP Quality Management Program, or the EU HACCP Program. A firm who is deemed unreliable may continue to use the mark or other applicable advertising privileges if consent by NOAA is given for daily auditing of the firm. Consent will be on a case by case basis and granted only if NOAA believes the nature of the condition which caused the firm to become unreliable warrants daily auditing. Daily auditing will be acceptable to NOAA under the following conditions:

a. The firm must submit a corrective action plan to the NOAA Consumer Safety Officer detailing how they will correct the problem (Faxes are acceptable). The corrective action plan must include, at a minimum, detailed descriptions of the following:

    1. A statement of the problem
    2. Identification of the person or persons handling the situation
    3. The methods to be used to correct the problem
    4. A schedule which details the time frame to correct the problem
    5. A statement with signatures of top management attesting to their commitment to correct the deficiency

    The corrective action plan must be written in sufficient detail to provide NOAA with all necessary information for its approval or disapproval.

b. The NOAA Consumer Safety Officer will review the corrective actions identified by the firm and will approve or disapprove the corrective actions and notify his/her Supervisor. Daily auditing will continue until the issue is corrected for a maximum of thirty calendar days.
c. Products may be certified during daily auditing. However, if any condition(s) exists that is considered critical, no product certification will occur until the condition is corrected to the satisfaction of NOAA.
d. At the inspector's discretion, product compliance will be verified by end-item inspection. No products covered by the QMP plan will leave the firm without NOAA approval.
e. Firms deemed unreliable twice in a twelve month period will be removed from the HACCP Quality Management Program or the EU HACCP Program.
f. Firms who have been removed from the HACCP Quality Management Program or the EU HACCP Program may submit a request for reapplication into the program after a period of three calendar months. Application will be accepted by NOAA only if evidence of a change in management philosophy can be provided.
g. Firms who have been removed from the NOAA HACCP Quality Management Program or EU HACCP Program may still be eligible to enter into the traditional Inspection Program.

Appeal Procedures

If a facility wishes to appeal this decision, they are to contact, in writing, the Chief Quality Officer in NOAA Seafood Inspection Program headquarters. The facility must provide, in writing, all pertinent information as to why it is believed the rating was determined in error and what the facility expects to be a proper correction. Once the Chief Quality Officer receives all information, he/she will investigate the matter and make a determination. The decision will be communicated to the Regional Inspection Branch and the facility as soon as it is made. A written report will follow.

Use of Marks

Participating firms are responsible for using the marks in accordance with the regulations set forth in 50 CFR Part 260 and the Policy and Guidelines for Advertising and Marking Products Inspected by the U.S. Department of Commerce. Facilities who have received official stamping devices must have written procedures in place securing the device and protecting from its abuse.

Analytical Testing and Product Verification

The firm must perform periodic end-item verification of product compliance to program requirements. Both the firm and NOAA must agree upon the firm's frequencies of testing and end-item product requirements, however, product samples for analytical testing must be collected and analyzed at least once per year as part of the firm's verification procedures. The level of analytical sampling per lot must also be comparable to that found in the Hazards and Controls Guide of the Food and Drug Administration. Records of all analytical findings will be made available to NOAA inspectors during Systems Audits and at other times as necessary. As part of the product verification discussed below, NOAA will have product tested analytically throughout the year. Six lots will be tested based upon the information found in the FDA Hazards and Controls Guide. Three lots will be tested for any criteria that is considered quality or economic integrity in nature, such as moisture content of scallops. Variation in the described sampling frequency may occur if evidence warrants. However, any changes to the frequency (and their effects) will be discussed with the applicable parties prior to their implementation.

To determine whether the product produced at the firm meets specification and/or U.S. grade standard requirements, NOAA will routinely perform a product audit on up to three (3) lots produced by the firm since the last Systems Audit. This information will be used to guide the auditor in his/her audit of the system. Product audits will be completed by conducting records reviews and finished product sample inspections. Additional lots may be sampled if the situation warrants. Lots must be defined by the firm in their QMP plan and approved by NOAA.

1.0 General Requirements

1.1 21 CFR Part 123

1.1.1 Hazard analysis not performed.

Every processor shall conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

The hazard and defect analysis is the foundation of the quality plan. If the analysis is not performed, the entire plan and its efficacy is suspect. Firms must provide this analysis to the requesting Consumer Safety Officer in writing. If it is not provided and evidence suggests that it was performed but a written document is not available, a Serious deficiency will only be assessed. Otherwise, a Critical deficiency will be assessed.

Deficiency: Serious/Critical

1.1.2 No written HACCP plan when one is required.

Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur. Firms must provide this plan to the requesting Consumer Safety Officer.

Deficiency: Serious

1.1.3 Plan is not location and/or fish species specific.

A HACCP plan shall be specific to:

1. Each location where fish and fishery products are processed by that processor; and
2. Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph are identical for all fish and fishery products so grouped or for all production methods so grouped.

Deficiency: Major

1.1.4 Hazard(s) is not listed in the plan.

The HACCP plan shall, at a minimum list the food safety hazards that are reasonably likely to occur and that thus must be controlled for each fish and fishery product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

1. Natural toxins;
2. Microbiological contamination;
3. Chemical contamination;
4. Pesticides;
5. Drug residues;
6. Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition;
7. Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels, or intends for the product to be so consumed;
8. Unapproved use of direct or indirect food or color additives; and
9. Physical hazards

Deficiency: Serious

1.1.5 Hazard(s) is not controlled.
Firms may not have met the requirements of performing the hazard analysis or writing a required HACCP plan. However, controls may still be in place for the hazards identified by the Consumer Safety Officer. If it is determined that the controls are not in place, a Critical deficiency will be assessed.
Deficiency: Critical

1.1.6 CCPs are not properly identified in the plan.
The HACCP plan shall, at a minimum list the critical control points for each of the identified food safety hazards, including as appropriate:
1. Critical control points designed to control food safety hazards that could be introduced in the processing plant environment; and
2. Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest.

Deficiency: Serious

1.1.7 Appropriate critical limit(s) is not listed in the plan.
The HACCP plan shall, at a minimum list the critical limits that must be met at each of the critical control points. If evidence is present that the critical limits were improperly identified but those identified were followed, the deficiency will be assessed here.
Deficiency: Serious

1.1.8 Monitoring procedure(s) in the plan is inadequate.
The HACCP plan shall, at a minimum, list the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits.
Deficiency: Serious

1.1.9 Corrective action listed in plan is not appropriate.
Whenever a deviation from a critical limit occurs, a processor shall take corrective action by following a corrective action plan that is appropriate for the particular deviation.
Deficiency: Serious

1.1.10 Verification procedure(s) stated in plan is inadequate.
The HACCP plan shall list the verification procedures, and frequency thereof, that the processor will use. Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented.

Verification shall include, at a minimum:
1. Reassessment of the HACCP plan. A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. Such changes may include changes in the following: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Sec. 123.10 of 21 CFR Part 123. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements.

2. Ongoing verification activities. Ongoing verification activities including:
   - A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;
   - The calibration of process-monitoring instruments; and,
   - At the option of the processor, the performing of periodic end-product or in-process testing.

3. Records review. A review, including signing and dating, by an individual who has been trained in accordance with Sec. 123.10, of the records that document:
   - The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;
   - The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with Sec. 123.7. This review shall occur within 1 week of the day that the records are made; and
   - The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

4. Processors shall immediately follow corrective action procedures whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action. (See Corrective Action sections listed below.)

5. Reassessment of the hazard analysis. Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food safety hazard now exists. Such changes may include, but are not limited to changes in: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been properly trained in accordance with 21 CFR 123.10. (See 2.3.1)

6. Recordkeeping. The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing shall be documented in records that are subject to recordkeeping requirements listed below.

Deficiency: Serious

1.1.11 Sanitation standard operating procedures not present.

Each processor should have and implement a written sanitation standard operating procedure (SSOP) or similar document that is specific to each location where fish and fishery products are produced. The SSOP should specify how the processor would meet those sanitation conditions and practices that are to be monitored.

Deficiency: Serious

1.1.12 Sanitation not monitored.

Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in 21 CFR Part 110 that are both appropriate to the plant and the food being processed and relate to the following:

1. Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;
2. Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;
3. Prevention of cross-contamination from unsanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;
4. Maintenance of hand washing, hand sanitizing, and toilet facilities;

5. Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;
6. Proper labeling, storage, and use of toxic compounds;
7. Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and
8. Exclusion of pests from the food plant.

Deficiency: Serious

1.2 Program Requirements

1.2.1 Defect Action Plan is not adequate to control product quality characteristics.

Every processor, as applicable, shall have and implement a written Defect Action Plan and a quality defect analysis for products that will either bear an inspection mark or will be advertised as under the NOAA Seafood Inspection Program. Firms must provide this plan to the requesting Consumer Safety Officer.

Deficiency: Critical

1.2.2 Quality Manual is inadequate.

Every processor, as applicable, shall have and implement a written quality manual which covers each of the elements delineated in the Quality System Requirements. Firms must provide this plan to the requesting Consumer Safety Officer.

Deficiency: Serious

1.2.3 Labels and/or specifications are inadequate.

Title 50 of the Code of Federal Regulations (CFR) requires that establishments contracting for fishery product inspection service obtain NOAA approval of labels prior to use on products packed under Federal inspection, regardless of whether or not they bear official inspection or grade marks. Additionally, the "Policy for Advertising Services and Marks" identifies additional labeling and advertising of marks and services that must be approved prior to use. The Regulations Governing Processed Fishery Products require that specifications for all products for which U.S. Standards for Grades are not available be approved by the Secretary of Commerce and that end-product samples, when requested, be evaluated to determine their compliance with approved specifications prior to NOAA inspection and certification of such products.

Deficiency: Serious

2.0 Adherence to HACCP-based Plan

2.1 Procedures

The procedures outlined in a firm's QMP plan must be followed as written. The plan was approved by NOAA as a whole, not procedure-by-procedure. Not following a procedure could affect the entire critical control point.

2.1.1 Monitoring procedures not followed:

Monitoring procedures must be followed to maintain control of the process. If any monitoring procedure has not been followed and a corrective action report is not filed, the firm is not in compliance with this item.

Deficiency: Serious

2.1.2 Critical limits not followed.

Self Explanatory.

Deficiency: Critical

2.1.3 Corrective action not taken

Whenever a deviation from a critical limit, sanitation, verification, or quality plan occurs, a processor shall take corrective action. Processors may develop written corrective action plans, which become part of their QMP plans by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

1. No product enters commerce that is either injurious to health, is otherwise adulterated as a result of the deviation, or does not meet Program requirements; and
2. The cause of the deviation is corrected.

A firm is provided room for error in their plan through a system of corrective actions. If an error or problem arises in the conducting of the QMP plan, the firm must file a corrective action report (Notice of Unusual Occurrence and Corrective Action--NUOCA). All other deficiencies may possibly be averted in this checklist if corrective action reports are filed for each problem or situation. Failure to file a corrective action report will be considered a failure to take a corrective action and the firm will then not be in compliance with this item.

When a deviation from the QMP occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

1. Segregate and hold the affected product.
2. Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review.
3. Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation or does not meet other program requirements;
4. Take corrective action, when necessary, to correct the cause of the deviation;
5. Perform or obtain timely reassessment by an individual or individuals who have been properly trained to do so, to determine whether the plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the plan as necessary.

Deficiency: Critical

2.1.4 Verification procedures not followed.
Verification procedures are those that provide for management to determine the overall effectiveness of the plan. Not following these procedures could ultimately cause the plan to fail or misidentify a hazard, defect, or control procedure. Since failure of these procedures will likely not immediately cause the plan to fail, it is rated at a Serious level. This item should be checked on a trend basis, not based on isolated incidences unless they are of such severity to warrant action. Firms must reassess their hazard and defect analyses when information or other evidence indicates the need and at least yearly. The plan must be signed and dated by a management official responsible for the operation of the facility. The plan must be signed upon implementation and at least once each year.

Deficiency: Serious

2.1.5 Sanitation standard operating procedures not followed.
This deficiency will be assessed if it is determined that the firm did not follow their written SSOPs, whether or not specific sanitation deficiencies were observed.

Deficiency: Serious

2.1.6 Defect action plan/quality manual not followed.
This deficiency will be assessed if the firm did not follow the policies outlined in their Quality manual or did not follow the procedures listed in their defect action plan. This deficiency will be assessed whether or not it was determined that product was affected.

Deficiency: Serious

2.2 Records

2.2.1 Inadequate information on records (Facility name and location, etc.)
Self Explanatory. Based on the required information stated in 21 CFR Part 123.
All records required by this part shall include:

1. The name and location of the processor or importer;
2. The date and time of the activity that the record reflects;
3. The signature or initials of the person performing the operation; and
4. Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.

Deficiency: Major

2.2.2 Record data is missing.
All records must be kept up-to-date. Entries must be made as they are measured. The records shall contain the actual values and observations obtained during monitoring or measurement. All time schedules outlined in the QMP plan must be maintained. Examples of non-compliance include: measurement observed to be taken but not entered on record; partial entry of information from monitoring procedures; initials for QA verification not recorded in a timely manner; etc. If record data is missing, a Major deficiency will be assessed.

All labels must be up-to-date. All labels must be kept on file by the firm. If labels are not up-to-date, a Serious deficiency will be assessed.

The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.
Deficiency: Major (Serious for Labels)

2.2.3 Records are inaccurate.
All entries must be accurate or the record is meaningless. If calculations, time test measured, etc., are not correct, the box for this deficiency should be checked. This deficiency will also be used for the compliance of product leaving the firm.
Deficiency: Serious/Critical

2.2.4 Records are not available for inspection.
If the firm for any unreasonable amount of time does not surrender the applicable record for inspector review, they are not in compliance with this item. If portions of a record are not available, the firm is not in compliance with this item. All required records shall be retained at the processing facility or importer's place of business in the United States for at least 1 year after the date they were prepared in the case of refrigerated products and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.

Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility or the importer's place of business in the United States for at least 2 years after their applicability to the product being produced at the facility.

If the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned for official review upon demand.
Deficiency: Critical

2.2.5 Documents or records are falsified.
This item is self-explanatory. However, intent on the part of the firm or its representatives must be shown. For example, if an item on a record was shown to be corrected with correction fluid or other means of obliteration, the inspector must show that someone with, full knowledge, changed the entry to reflect a value that was not the value measured or observed. Otherwise, this will be considered an inaccurate entry.
Deficiency: Critical

2.3 Other Requirements
2.3.1 Program trained personnel not available. Hazard analysis, reassessment or modification of HACCP plan, or records review performed by untrained personnel.
Each firm must employ a person who has been certified by NOAA for this program. At least one NOAA HACCP-certified person is required to be present during production. In addition, copies of all certified personnel's certificates must on file with the firm. Per 21 CFR part 123, these duties are assigned only to properly trained personnel. For the QMP Program, properly trained will be any person who has passed the NOAA Certification Exam. However, failure of this element will not likely cause an immediate hazard or defect. Therefore it is rated as a Serious deficiency. Per 21 CFR part 123, these

duties are assigned to only properly trained personnel. Failure of this element could lead to an immediate hazard or defect.

At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing at least equivalent to that received under standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.

- Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of Sec. 123.6(b);
- Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in Sec. 123.7(c)(5), the HACCP plan in accordance with the verification activities specified in Sec. 123.8(a)(1), and the hazard analysis in accordance with the verification activities specified in Sec. 123.8(c); and
- Performing the record review required by Sec. 123.8(a)(3). The trained individual need not be an employee of the processor.

Deficiency: Serious

2.3.2 Modification to QMP plan without approval.

Any change in procedures whether they are written or not will be considered non-compliance by the firm for this item. This includes all procedures at critical control points, sanitation procedures, recall procedures verification procedures, and consumer complaint procedures. Exceptions will be allowed for those procedures the firm can justify that were necessary to avert or control a public safety or health situation provided a corrective action report is on file for the incident and a request for plan modification is filed with the servicing NOAA Regional Inspection Branch within a 24-hour period.

Deficiency: Serious

3.0 Facility Sanitation

References: 21 CFR Part 110; 21 CFR Part 123.11(b)

3.1 Safety of Process Water

Process water must be of very high quality as it directly interfaces or becomes part of the product being manufactured. Therefore, no filth, deleterious chemicals, bacteria, or other contaminants may be present in solution as it will directly affect the safety of the product. Available water must pass potability standards established by federal, state, and local authorities. Water that is supplied to the plant must meet certain minimum standards. However, processing water must also be reasonably protected in the facility. Conditions that allow contamination to occur cannot be allowed. These may include cross-connection of plumbing, back-siphonage, or back flow from a contaminated source to the supply system or open vessels of water.

3.1.1 Unsafe or unsanitary water supply.

The water supply, including seawater, will be in compliance when by certification or direct testing the supply is found to meet the federal standards set forth by the Environmental Protection Agency. Private supplies shall have testing performed at a minimum of every six (6) months. Certification of municipal or community systems should be secured at a minimum of once per year.

Deficiency: Critical

3.1.2 No protection against backflow, back-siphonage, or other sources of contamination.

A facility will be in compliance when all cross-connections are eliminated, backflow prevention devices are installed wherever backflow or siphonage may occur, or where other possible forms of contamination may be present.

Deficiency: Serious

3.1.3 Inadequate supply of hot water.
Hot water is necessary for many cleaning techniques. In addition, a hot water supply is necessary to provide a comfortable means for employees to wash their hands. If the tap is on and a luke-warm supply of water is present in sufficient quantities for the tasks it will perform in the facility, the plant is in compliance. The supply must also be easily accessible for its proper use.
Deficiency: Minor

3.1.4 Ice not manufactured, handled, or used in a sanitary manner.
A facility will be in compliance when potable water is used for manufacturing, when the manufacturing equipment is clean, and the ice only touches impervious surfaces; the ice holding containers are clean and made of appropriate impervious material; handling equipment is clean and appropriate for food contact; and ice is not reused on ready-to-eat product. For facilities receiving ice from an outside supply, a certificate of conformance will be necessary to ensure that the ice being received meets the standards set forth in this document. In addition, potability checks must be made at a minimum of every six (6) months on ice received.
Deficiency: Critical

3.2. Food Contact Surfaces
3.2.1 Equipment and utensils' design, construction, location, or materials cannot be readily cleaned and sanitized; does not preclude product adulteration or contamination.
Any equipment used in the manufacturing or handling of the food product must be designed or constructed so that it can be easily taken apart for regular cleaning and inspection. Failure to do so will cause the facility to be out of compliance. In addition, if the materials used are not of a material suitable for its intended purpose or there is reuse of single-service items, then the facility is also out of compliance.
Deficiency: Major

3.2.2 Equipment, primary packaging materials, and utensils not maintained in proper repair or removed when necessary. (Product-contact surfaces)
All product contact surfaces must be kept in good repair. If the contact surface cannot be repaired, then the piece of equipment or utensil should be removed so as not to allow for its use. Primary packaging materials should be adequately covered when stored or not in use. Failure to provide these conditions will result in non-compliance.
Deficiency: Major (Serious for products at a high risk stage of processing)

3.2.3 Product contact surfaces not cleaned or sanitized before use, after interruptions, or as necessary.
Product contact surfaces must be cleaned using proper techniques to remove dirt and debris. Sanitizers must be used before product contacts the surface. Sanitizing without cleaning is insufficient. Any violation will be considered non-compliance.
Deficiency: Serious (Critical for products at a high risk stage of processing)

3.2.4 Processing or food handling personnel do not maintain a high degree of personal cleanliness.
All persons, while in food preparation or handling areas shall wear clean outer garments, use clean cloths, and conform to hygienic practices while on duty, to the extent necessary to prevent contamination or adulteration of food. This includes occasional workers or visitors to the area.
Deficiency: Major/Serious

3.2.5 Processing or food handling personnel do not take necessary precautions to prevent adulteration or contamination of food.
All persons, while in a food preparation or handling area, shall:

1. Wash their hands thoroughly to prevent contamination by undesirable microorganisms before starting work, after each absence from

the work station, and at any other time when the hands may have become soiled or contaminated. After washing, the hands must be sanitized using the company-provided hand dip stations.

2. Remove all insecure jewelry, and when food is being manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized.

3. If gloves are used in food handling, maintain them in an intact, clean, and sanitary condition. Such gloves shall be of an impermeable material except where their usage would be inappropriate or incompatible with the work involved. If gloves are used they will be washed and sanitized at the same frequency as employees' hands as described in number one of this list.

4. Wear hair nets, caps, masks, or other effective hair restraint. Other persons that may incidentally enter the processing areas shall comply with this requirement.

5. Not expectorate; nor store clothing or other personal belongings; not eat food or drink beverages; nor use tobacco in any form in areas where food or food ingredients are exposed, or in areas used for food processing, storage of food ingredients and/or packaging materials, washing of equipment and utensils, or in production areas.

6. Take other necessary precautions to prevent contamination of foods with microorganisms or foreign substances including, but not limited to perspiration, hair, cosmetics, tobacco, chemicals, and medicants.

Deficiency: Serious/Critical

3.3. Prevention of Cross Contamination

3.3.1 Grounds condition can permit contamination to enter the facility.

There shall be no conditions on the grounds such as dusty roads or parking lots, mud puddles, chemical spills, etc., that can cause contamination to be carried into the plant through such means as wind drafts, personnel foot traffic, adherence to personnel clothing, flooding, etc. Design of the facility structure should be such that access is easily obtained to all areas. This is necessary for proper cleaning and sanitizing of floors, walls and ceilings, as well as for visual inspections.

Deficiency: Minor

3.3.2 Facility

3.3.2.1 Design, layout of materials used cannot be readily cleaned and sanitized; does not preclude product adulteration or contamination.

If the rooms (including restrooms and employee breakrooms) in the facility are laid out or designed in such a way that they cannot be readily cleaned or sanitized, then the facility is not in compliance. This would include improper materials for walls, ceilings, etc., as well as hard-to-reach rooms or corners even when the equipment is removed from the room.

Deficiency: Major

3.3.2.2 Insufficient separation by space or other means allows product to be adulterated or contaminated.

There must be sufficient separation between different activities in the processing, packaging and handling of food products. This includes the complete separation of living/sleeping quarters or heavy maintenance areas from food-handling areas. The food product should flow easily from one stage to another and not be allowed to come into contact with non-food surfaces if exposed. In addition, the layout of the facility should not be such that product contamination is likely due to heavy employee traffic through work areas.

Retail product displays should be arranged so that there is sufficient separation to assure that no cross-contamination can occur between raw, cooked, and live product.

Deficiency: Serious (Critical for products at a high risk stage of production)

3.3.3 Condition of roof, ceilings, walls, floors, or lighting not maintained; lights not protected.

3.3.3.1 Areas directly affecting product or packaging material.

For those areas that will directly affect product or primary packaging materials, (packaging immediately surrounding product), the roof, ceiling, walls, floors, and lighting fixtures must be maintained as designed and lights must be protected. Failure to do so causes the facility to be out of compliance.

Deficiency: Critical

3.3.3.2 Other.

For areas in the facility other than in 3.3.3.1 above, the roof, ceilings, walls, floors, or lighting fixtures must also be maintained as designed. This does not include those areas designated as offices and in which food products or primary packaging materials in any stage of production will not be handled or stored.

Deficiency: Minor (Major for products at a high risk stage of production)

3.3.4 Cleaning methods permit adulteration or contamination.

Employees must take care to use methods that will not adulterate or contaminate the product. Any cleaning or sanitizing procedures or techniques that may cause the product to become adulterated or contaminated will caused the facility to be in non-compliance. Examples of non-compliance include but are not limited to inadvertent touching of product or product surfaces with wash water, detergent, sanitizers, etc., during production.

Deficiency: Serious (Critical for products at a high risk stage of production)

3.3.5 Finished product not properly covered or protected.

Finished product must be either packaged, covered or protected so as to not permit contamination or adulteration prior to shipment.

Deficiency: Major (Serious for products at a high risk stage of production)

3.3.6 Equipment and utensils not maintained in proper repair or removed when necessary. (Non-product contact surfaces)

All non-food contact surfaces should also be maintained in good repair. The facility is in non-compliance when the maintenance of all additional equipment or areas of equipment and utensils not referred to in item 3.2.1 above is insufficient and may allow indirect product contamination or adulteration.

Deficiency: Minor (Major for products at a high risk stage of production)

3.3.7 Non-product contact surfaces not cleaned before use.

Non-product contact areas must also be cleaned prior to use. However, sanitizing is not required. This includes wall, ceilings, floors, and other room areas as well as equipment.

Deficiency: Major

3.4. Handwashing, Hand Sanitizing, and Toilet Facilities

3.4.1 Hand washing and hand sanitizing stations not present or conveniently located.

Hand washing and hand sanitizing stations must be present and located conveniently and in sufficient numbers to provide employees ease of their use.

Deficiency: Serious (Critical for products at a high risk stage of production)

3.4.2 Improper disposal of Sewage.

A facility is in compliance when sewage systems drain properly, are vented to the outside, and are connected to an approved private septic system or a public septic and/or sewerage system.

Deficiency: Critical

3.4.3 Inadequate supplies.

The restrooms must provide supplies such as toilet paper, soap, etc., sufficient enough to meet employees' needs.

Deficiency: Major

3.4.4 Insufficient number of functional toilets.

The facility must have one operable, in good repair, conveniently accessible toilet per fifteen (15) employees, per gender. For men, urinals may be substituted for toilet bowls, but only to the extent of one-third (1/3) of the total number of bowls required.

Deficiency: Minor

3.5. Protection From Adulteration

3.5.1 Condensation.

3.5.1.1 Areas directly affecting product or primary packaging material.

If any condensation, overhead leaks, or water splash is found in areas in the facility where the condensation has the potential to come in contact with product or primary packaging material, the facility is in non-compliance.

Deficiency: Serious (Critical for products at a high risk stage of production)

3.5.1.2 Other

Any areas other than those noted above where food is stored, handled, processed, packaged, or displayed shall be condensation-free. If condensation is noted in these areas, the facility shall be in non-compliance.

Deficiency: Major

3.5.2 Adequate air exchange does not exist.

A facility is in compliance when adequate air exchange exists to preclude the development of foul odors.

Deficiency: Minor (Only for products at a high risk stage of production)

3.6. Proper Labeling, Use, and Storage of Toxic Compounds

Plant chemicals are cleaners, sanitizers, rodenticides, insecticides, machine lubricants, etc. They must be used according to manufacturer's instructions, have proper labeling, and be stored in a safe manner or they may pose a risk of contaminating the food product that the establishment is handling or manufacturing.

A facility will be in compliance when the chemicals are used according to manufacturer's instructions and recommendations and stored in an area of limited access away from food handling or manufacturing. All chemicals must be labeled to show the name of the manufacturer, instructions for use, and the appropriate EPA or USDA approval.

3.6.1 Chemical(s) improperly used or handled.

Deficiency: Critical

3.6.2 Chemical(s) improperly stored.

Deficiency: Serious

3.6.3 Chemical(s) improperly labeled.

Deficiency: Major

3.7. Control of Employee Health Conditions

3.7.1 Facility management does not have in effect measures to restrict people with known disease from contaminating the product.

No person affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds, or other abnormal sources of microbiological contamination, shall work in a food plant in any capacity in which there is a reasonable possibility of food or food ingredients becoming contaminated by such person. Plant management shall require employees to report illness or injury to supervisors.

Deficiency: Serious

3.8. Exclusion of Pests

The presence of rodents, insects, and other animals in the facility must not be allowed because they are sources for the contamination of food with foreign material, filth, and bacteria, etc.

3.8.1 Harborage and attractant areas present.

The facility and grounds are free of harborage areas. These include but are not limited to: uncut weeds, brush or tall grass; improper storage of unused equipment or materials; presence of litter, waste and refuse; or standing or stagnant water.

All garbage and refuse containers are rodent/insect-resistant and outside storage areas are properly constructed.

Deficiency: Major

3.8.2 Pest control measures not effective.

3.8.2.1 Exclusion

Openings to the outside of or within the facility may allow vermin or other pests to enter. Openings and cracks should be screened or otherwise sealed. Screens must be of a mesh not larger than 1/16th of an inch in order to exclude insects. Cracks or holes should be sealed and doors and windows should close tightly (no opening larger than 1/4 ") to exclude rodents or other animals. Air curtains and strip curtains must be effective. Air curtains shall comply with National Sanitation Standard Number 37 for Air Curtains for entranceways in food establishments. Strip curtains must run the entire width of the opening with sufficient overlap between flaps (1/2 inch). In addition, every effort should be made to keep birds from areas of the plant where food is transferred or processed.

Deficiency: Major

3.8.2.2 Extermination

Birds--Nesting areas must be eliminated.

Insects--There should not be a significant number of insects present in the facility. Insect electrocution devices, when used, must be located near the entranceway. Approved insecticides should be used whenever insect populations become noticeable.

Rodents--There should not be evidence of rodent activity. Evidence of rodents includes, but is not limited to: fecal droppings present; urine stains on bags or walls; slide marks along rodent runways; or feeding areas around stored dry goods bags that may be excessive. The facility should have appropriate rodent control measures in place. If not, the facility is not in compliance.

Deficiency: Serious

3.8.3 Inadequate disposal of processing waste.

A facility is in compliance with regard to processing wastes when they are placed in proper containers, placed at appropriate locations throughout the plant, and removed frequently.

Deficiency: Serious

3.8.4 Inadequate housekeeping.

Any excess clutter in production areas, employee areas, or other areas of the facility will cause the facility to be in non-compliance. This does not include those areas designated as office areas.

Deficiency: Minor

NOAA Seafood Inspection Program
Quality System Standard

1.0 MANAGEMENT RESPONSIBILITY

1.1 Quality Policy

Management with executive responsibility in the firm must endorse a policy statement that fully reflects company policy and objectives relating to quality (including the control of the safety, wholesomeness and integrity of the product), and its commitment to quality assurance. The policy must consider the expectations and needs of the customer. There must be a procedure to ensure the quality policy is known, understood, implemented, and maintained at all levels of the company.

1.2 Organization

The company shall establish and maintain an adequate organizational structure to ensure that the applicable fish and fishery products are designed and produced in accordance with the requirements of this standard.

1.2.1 Responsibility and Authority

The manufacturer shall establish and document the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and verify work affecting quality, and provide the independence and authority necessary to perform tasks including but not limited to:

a) Initiate action to prevent the occurrence of any nonconformities relating to the product, process, and quality system;
b) Identify and record any problems relating to the product, process, and quality system;
c) Initiate, recommend, or provide solutions through designated channels;
d) Verify the implementation of solutions;
e) Control further processing or delivery of nonconforming product until the deficiency or deficiencies have been corrected.

1.2.2 Resources

Each manufacturer shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and verification activities, including internal quality audits, to meet the requirements of this standard.

1.2.3 Management Representative

Management with executive responsibility shall appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority and responsibility for:

a) Ensuring that quality system requirements are effectively established, implemented, and effectively maintained in accordance with this standard; and
b) Reporting on the performance of the quality system to management with executive responsibility for review and as a basis for improvement of the quality system.
c) liaison with external parties on matters relating to the quality system.

1.3 Management Review

Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this standard and the manufacturer's established quality policy and objectives. The dates and results of quality system reviews shall be documented.

2.0 QUALITY SYSTEM

2.1 General

The manufacturer shall establish, document, and maintain a quality system that that ensures all applicable fish and fishery products conform to specified product standards and requirements and this standard. The manufacturer shall prepare a quality manual covering the requirements of this standard. The quality manual shall make reference to the quality system procedures and outline the structure of the documentation used in the quality system.

2.2 Quality System Procedures

The manufacturer shall:

a) prepare documented procedures consistent with the requirements of this standard and the manufacturer's stated quality policy, and
b) effectively implement the quality system and its documented procedures.

The range and detail of the procedures will depend on the complexity of the work, the methods used, and the skills and training needed by the personnel involved in carrying out the referenced activity. Documented procedures may make reference to work instructions that define how an activity is performed.

2.3 Quality Planning

The manufacturer shall establish how the requirements for quality will be met. Quality planning shall be consistent with all other requirements of the quality system and shall be documented in a format to suit the method of operation. The manufacturer shall give consideration to the following activities, as appropriate, in meeting the specified standards and requirements for fish and fishery products:

a) the quality and safety objectives to be attained;
b) the specific allocation of responsibilities and authority during the development, implementation, and maintenance of the system;
c) the specific procedures, methods and work instructions to be applied;
d) the specific tasks required for application of a HACCP system;
e) suitable testing, inspection, examination and audit programs at appropriate stages;
f) a method for making changes and modifications in a HACCP or quality plan as the are developed and implemented;
g) other measures to meet necessary objectives such as methods for meeting requirements of Good Manufacturing Practices (GMPs).

3.0 CONTRACT REVIEW

3.1 General

The manufacturer shall establish and maintain documented procedures for contract review and for the coordination of these activities.

3.2 Review

Before submission or the acceptance of a contract or order (statement of requirement), the contract or order shall be reviewed by the manufacturer to ensure that:

a) the requirements are adequately defined and documented; where no written statement of requirement is available for an order received by verbal means, the manufacturer shall ensure that the order requirements are agreed before their acceptance;
b) any differences of understanding of the contract or accepted order requirements are resolved;
c) the manufacturer has the capability to meet the contract or accepted order requirements.

3.3 Amendment to Contract

The manufacturer shall identify how an amendment to a contract is made and correctly transferred to the functions concerned within the organization.

3.4 Records

Records of contract reviews shall be maintained.

4.0 DESIGN CONTROL

4.1 General

The manufacturer shall establish and maintain documented procedures for translating the customer's specifications and requirements into technical specifications for raw materials, processing, packaging, storage, etc., and their verification. The specifications must also cover buildings, equipment and facilities (internal and external) where relevant. Responsibility for developing these specifications must be assigned to specific people and there must be a planned approach to each activity.

4.2 Design and Development Planning

The manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall be reviewed, updated, and approved as design and development evolves. These activities shall be assigned to qualified personnel equipped with adequate resources. The plans shall be updated as necessary.

4.3 Organizational and Technical Interfaces

The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process.

4.4 Design Input

The manufacturer shall establish and maintain procedures to ensure that the design requirements relating to the applicable fish and fishery product are appropriate and address the intended use by the purchaser or consumer. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.

4.5 Design Output

The manufacturer shall establish and maintain procedures for defining and documenting design output in terms that can be verified. Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the safety, wholesomeness, economic integrity, and quality of the fish or fishery product are identified. Design output shall be documented, reviewed, and approved before release. The approval, including the date and signature of the individual(s) approving the output, shall be documented.

4.6 Design Review

The manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the product's design development. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed. Records of such reviews shall be maintained.

4.7 Design Verification

The manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the verification shall be recorded.

4.8 Design Validation

Design validation shall be performed to ensure that product conforms to defined user needs, requirements, and intended use. Design validation shall include risk analysis where appropriate. Validation is normally performed on the final product, but may be performed in earlier stages prior to product completion. Multiple validations may be necessary if there are different intended end uses.

4.9 Design Changes

All design changes and modifications shall be identified, documented, reviewed, and approved by authorized personnel before their implementation.

5.0 DOCUMENT AND DATA CONTROL

5.1 General

The manufacturer shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this standard including, to the extent applicable, documents of external origin such as standards and customer specifications. Documents and data can be in the form of any type of media, such as hard copy or electronic media.

5.2 Document and Data Approval and Issue

The documents and data shall be reviewed and approved for adequacy by authorized personnel prior to issue. A master list or equivalent document-control procedure identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

This control shall ensure that:

a) the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;
b) invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;
c) any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified.

5.3 Document and Data Changes

Changes to documents and data shall be reviewed and approved by the same functions/organizati6ns that performed the original review and approval, unless specifically designated otherwise. The designated functions/organizations shall have access to pertinent background information upon which to base their review and approval. Where practicable, the nature of the change shall be identified in the document or the appropriate attachments.

6.0 PURCHASING

6.1 General

The manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.

6.2 Evaluation of Suppliers, Contractors, and Consultants

The manufacturer shall establish and maintain the requirements (including safety, wholesomeness, economic integrity, and quality requirements) that must be met by suppliers, contractors, and consultants. The manufacturer shall:

a) Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.
b) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results. This shall be dependent upon the type of product, the impact of subcontracted product on the quality of final product, and, where applicable, on the quality audit reports and/or quality records of the previously demonstrated capability and performance of subcontractors.
c) Establish and maintain quality records of acceptable suppliers, contractors, and consultants.

6.3 Purchasing Data

The manufacturer shall establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services. Purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and consultants agree to notify the manufacturer of changes in the product or service so that manufacturers may determine whether the changes may affect the quality of a finished product. The manufacturer shall review and approve purchasing documents for adequacy of the specified requirements prior to release.

6.3 Verification of Purchased Product

6.3.1 Supplier Verification at Subcontractor's Premises

Where the manufacturer proposes to verify purchased product at the subcontractor's

premises, the manufacturer shall specify verification arrangements and the method of product release in the purchasing documents.

6.3.2 Customer Verification of Subcontracted Product

Where specified in the contract, the manufacturer's customer or the customer's representative shall be afforded the right to verify at the subcontractor's premises, and the manufacturer's premises that subcontracted product conforms to specified requirements. Such verification shall not be used by the manufacturer as evidence of effective control of quality by the subcontractor.

Verification by the customer shall not absolve the supplier of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

7.0 CONTROL OF CUSTOMER-SUPPLIED PRODUCT

The manufacturer shall establish and maintain documented procedures for the control of verification, storage, and maintenance of customer-supplied product provided for incorporation into the supplies or for related activities. Any such product that is lost, damaged, or is otherwise unsuitable for use shall be recorded and reported to the customer.

Verification by the manufacturer does not absolve the customer of the responsibility to provide acceptable product.

8.0 PRODUCT IDENTIFICATION AND TRACEABILITY

8.1 Identification

The manufacturer shall establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation.

8.2 Traceability

The manufacturer shall establish and maintain documented procedures for unique identification of individual product, batches, or lots. This identification shall be recorded.

9.0 PROCESS CONTROL

The manufacturer shall identify and plan the production of processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions. Controlled conditions shall include the following:

a) documented procedures defining the manner of production where the absence of such procedures could adversely affect quality;
b) use of suitable equipment, and a suitable working environment;
c) compliance with reference standards/codes, quality plans, and/or documented procedures;
d) monitoring and control of suitable process parameters and product characteristics;
e) the approval of processes and equipment, as appropriate;
f) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples, or illustrations);
g) suitable maintenance of equipment to ensure continuing process capability.

Where the results of processes cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, the processes shall be carried out by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure that the specified requirements are met.

The requirements for any qualification of process operations, including associated equipment and personnel, shall be specified.

Records shall be maintained for qualified processes, equipment, and personnel, as appropriate.

10.0 INSPECTION AND TESTING

10.1 General

The manufacturer shall establish and maintain documented procedures for inspection and testing activities in order to verify that the

specified requirements for the product are met. The required inspection and testing, and the records to be established, shall be detailed in the quality plan or documented procedures.

10.2 Receiving Inspection and Testing

10.2.1 The manufacturer shall ensure that incoming product is not used or processed (except in the circumstances described in 4.10.2.3) until it has been inspected or otherwise verified as conforming to specified requirements. Verification of the specified requirements shall be in accordance with the quality plan and/or documented procedures.

10.2.2 In determining the amount and nature of receiving inspection, consideration shall be given to the amount of control exercised at the subcontractor's premises and the recorded evidence of conformance provided.

10.2.3 Where incoming product is released for urgent production purposes prior to verification, it shall be positively identified and recorded in order to permit immediate recall and replacement in the event of nonconformity to specified requirements.

10.3 In-process Inspection and Testing

The manufacturer shall:

a) inspect and test the product as required by the quality plan and/or documented procedures;

b) hold product until the required inspection and tests have been completed or necessary reports have been received and verified, except when product is released under positive-recall procedures (see 10.2.3). Release under positive-recall procedures shall not preclude the activities outlined in 10.3a.

10.4 Final inspection and testing

The manufacturer shall carry out all final inspection and testing in accordance with the quality plan and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.

The quality plan and/or documented procedures for final inspection and testing shall require that all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and that the results meet specified requirements.

No product shall be dispatched until all the activities specified in the quality plan and/or documented procedures have been satisfactorily completed and the associated data and documentation are available and authorized.

10.5 Inspection and Test Records

The manufacturer shall establish and maintain records which provide evidence that the product has been inspected and/or tested. These records shall show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming product shall apply (see 4.13).

Records shall identify the inspection authority responsible for the release of product (see 4.16).

11.0 CONTROL OF INSPECTION, MEASURING, AND TEST EQUIPMENT

The manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. The manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained. The procedures shall include provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained. These activities shall be documented.

Calibration procedures shall include specific directions and limits for accuracy and precision. When accuracy and precision limits are not met, there shall be provisions for remedial action to reestablish the limits and to evaluate whether

there was any adverse effect on the device's quality. These activities shall be documented.

Calibration standards used for inspection, measuring, and test equipment shall be traceable to national or international standards. If national or international standards are not practical or available, the manufacturer shall use an independent reproducible standard. If no applicable standard exists, the manufacturer shall establish and maintain an in-house standard.

The equipment identification, calibration dates, the individual performing each calibration, and the next calibration date shall be documented. These records shall be displayed on or near each piece of equipment or shall be readily available to the personnel using such equipment and to the individuals responsible for calibrating the equipment.

12.0 INSPECTION AND TEST STATUS

The inspection and test status of product shall be identified by suitable means, which indicate the conformance or nonconformance of product with regard to inspection and tests performed. The identification of inspection and test status shall be maintained, as defined in the quality plan and/or documented procedures, throughout production, installation, and servicing of the product to ensure that only product that has passed the required inspections and tests [or released under an authorized concession (see 13.2)] is dispatched, used, or installed.

13.0 CONTROL OF NONCONFORMING PRODUCT

13.1 General

The manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented.

13.2 Review and Disposition of Nonconforming Product

The manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.

The manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented.

14.0 CORRECTIVE AND PREVENTIVE ACTION

14.1 General

The manufacturer shall establish and maintain documented procedures for implementing corrective and preventive action.

Any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.

The manufacturer shall implement and record any changes to the documented procedures resulting from corrective and preventive action.

14.2 Corrective Action

The procedures for corrective action shall include:

a) the effective handling of customer complaints and reports of product nonconformities;

b) investigation of the cause of nonconformities relating to product, process, and quality System, and recording the results of the investigation (see 16);
c) determination of the corrective action needed to eliminate the cause of nonconformities;
d) application of controls to ensure that corrective action is taken and that it is effective.

14.3 Preventive Action

The procedures for preventive action shall include:

a) the use of appropriate sources of information such as processes and work operations which affect product quality, concessions, audit results, quality records, service reports, and customer complaints to detect, analyze, and eliminate potential causes of nonconformities;
b) determination of the steps needed to deal with any problems requiring preventive action;
c) initiation of preventive action and application of controls to ensure that it is effective;
d) confirmation that relevant information on actions taken is submitted for management review (see 1.3).

15.0 HANDLING, STORAGE, PACKAGING, PRESERVATION, AND DELIVERY

15.1 General

The manufacturer shall establish and maintain documented procedures for handling, storage, packaging, preservation, and delivery of product.

15.2 Handling

The manufacturer shall provide methods of handling product that prevent damage or deterioration.

15.3 Storage

The manufacturer shall use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated.

In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals.

15.4 Packaging

The manufacturer shall control packing, packaging, and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.

15.5 Preservation

The manufacturer shall apply appropriate methods for preservation and segregation of product when the product is under the supplier's control.

15.6 Delivery

The manufacturer shall arrange for the protection of the quality of product after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination.

16.0 CONTROL OF QUALITY RECORDS

The manufacturer shall establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records.

Quality records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent quality records from the subcontractor shall be an element of these data.

All quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of quality records shall be established and recorded. Where agreed contractually, quality records shall be made available for evaluation by the customer or the customer's representative for an agreed period.

Records may be in the form of any type of media, such as hard copy or electronic media.

17.0 INTERNAL QUALITY AUDITS

The manufacturer shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.

Internal quality audits shall be scheduled on the basis of the status and importance of the activity to be audited and shall be carried out by personnel independent of those having direct responsibility for the activity being audited.

The results of the audits shall be recorded (see 16) and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on deficiencies found during the audit.

Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken (see 16).

18.0 TRAINING

The manufacturer shall establish and maintain documented procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as required. Appropriate records of training shall be maintained (see 16).

19.0 SERVICING

Where servicing is a specified requirement, the manufacturer shall establish and maintain documented procedures for performing, verifying, and reporting that the servicing meets the specified requirements.

20.0 STATISTICAL TECHNIQUES

20.1 Identification of Need

The manufacturer shall identify the need for statistical techniques required for establishing, controlling, and verifying process capability and product characteristics.

20.2 Procedures

The manufacturer shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified in 20.1.

I. SUBJECT: Label Review/Approval Procedures and Submittal Instructions

II. AUTHORITY: 50 CFR 260.97(c)(12), (13), (15), (16)

III. PURPOSE: To establish standard procedures for processing fishery product labels submitted by official establishments for NMFS approval; present the new procedures for label review/approval; standardize the temporary approval and disapproval criteria; and identify and define the instances when label approval will be charged to the submitting establishments.

IV. GENERAL.

A. Title 50 of the Code of Federal Regulations (CFR) requires that establishments contracting for fishery product inspection service obtain NMFS approval of labels prior to use on products packed under Federal inspection, regardless of whether or not they bear official inspection or grade marks. Additionally, "Policy for Advertising Services and Marks", NOAA Inspection Manual 25, Part III, Chapter 1, Section 01, identify additional labeling and advertising of marks and services that must be approved prior to use. Exceptions to this requirement are noted below. Procedures for Child Nutrition (CN) label approval are found in NOAA Inspection Manual 25, Part I, Chapter 3, Section 11.

EXCEPTIONS: This procedure does not apply to products inspected and certified for the Defense Personnel Support Center (DPSC) or other Federal agencies that have specific labeling requirements. However, we recommend that these labels be submitted for review and record-keeping purposes.

B. The Approving Officer, Inspection Services Division, Technical Services Branch, Documentation Approval and Supply Service Section (DASS), Pascagoula, MS, is responsible for administering the Label Review/Approval System and assuring that this system is operational. The authority to approve institutional and case labels is delegated to the Regional Consumer Safety Officers (CSO).

C. Processing specifications for all nonstandardized products shall be submitted for approval concurrently with labels. See

NOAA Inspection Manual 25, Part I, Chapter 3, Section 08, Product Specifications for Nonstandardized Products. A copy of previously approved specifications must be submitted with each label submittal.

V. SUBMITTAL INSTRUCTIONS.

A. Contracting Party

1. New and revised labels: The processor is required to submit four label proofs and/or finished labels (CN labeling requires five), prior to use, to the assigned Consumer Safety Inspector (CSI)/Consumer Safety Officer (CSO) or supervisory CSO. Proofs of new or revised labels are not required, but are encouraged. Proof review affords establishments the opportunity to obtain information on the compliance of the proof with labeling regulations and may prevent modification to finished labels thus reducing costs.

2. Cancellations: When products are withdrawn from inspection, a completed NOAA Form 89-819, Specification and Label Submittal Action Request, indicating the label approval number, specification number, and approval date is submitted to the assigned CSI/CSO or supervisory CSO for signature. Establishments are encouraged to submit a copy of the original NOAA Form 89-819 on which the label was approved to expedite the process.

3. All submittals must be accompanied by NOAA Form 89-819 through the assigned CSI/CSO, or through the immediate supervisor when the CSI/CSO is not available. (See Attachment 1). It is the responsibility of the submitting establishment to complete the NOAA Form 89-819 prior to submitting the package to the assigned CSI/CSO for review. Establishments are reminded to complete separate NOAA Forms 89-819 for institutional labels, case labels (nonretail), retail labels and CN labels. Only one group, for example retail labels, are to be submitted on a NOAA Form 89-819. Use another NOAA Form 89-819 for submitting CN labels and do likewise for institutional and/or case labels. Further, there are to be no more than four different labels of the same group, e.g., institutional labels, on one NOAA Form 89-819.

Note: For purposes of this manual release, retail labels

are defined as any label bearing mandatory nutrition labeling.

4. In the absence of the assigned CSI/CSO, Block 10, USDC Inspector's signature, may be left blank and a statement placed in Block 13, Remarks, indicating the name of the CSI/CSO's supervisor with whom submittal was discussed and who authorized the submittal. Such submittals will be verified by the Regional Label Approval CSO or the Approving Officer.

5. HACCP-based Inspection Establishments are not required to have the NOAA Form 89-819 signed by a CSI/CSO or supervisory CSO. Such establishments may submit labels, depending on group or type, with the form directly to the Regional Label Approval CSO or the Approving Officer.

6. After review and signature by the assigned CSI/CSO, the establishment is responsible for mailing the submittal package (labels, specifications, and NOAA Form 89-819). Institutional and case labels are mailed to the identified Regional Label Approval CSO, and retail and CN labels are mailed to the Approving Officer.

7. Regional Consumer Safety Officers duty stations

a. Northeast Region

Consumer Safety Officer-Label Review/Approval
National Marine Fisheries Service
Northeast Inspection Branch
One Blackburn Drive
Gloucester, MA 01930
Phone (978) 281-9292
Fax (978) 281-9134

b. Southeast Region

Consumer Safety Officer-Label Review/Approval
National Marine Fisheries Service
Tampa Lot Inspection Office

Attn Label Review
1601 North 50th Street
Tampa, FL 33619
Phone (813) 228-2546
Fax (813) 228-2980

c. Western Region

Consumer Safety Officer-Label Review/Approval
National Marine Fisheries Service
Western Inspection Branch
5600 Rickenbacker Road, Bldg. 7
Bell, CA 90201
Phone (323) 526-7412
Fax (323) 526-7417

8. Approving Officer
USDC, NMFS
Inspection Service Division
Technical Services Branch
Documentation Approval and Supply Service Section
3207 Frederic Street, Suite B
P. O. Drawer 1207
Pascagoula, MS 39568-1207

B. NMFS CSI or CSO

The assigned CSI or CSO will:

1. assure that only those label proofs and/or finished labels which have been authorized for submittal by a properly designated official of the establishment are sent to the Regional Label Approval CSO or Approving Officer, and that separate NOAA Form 89-819's are completed for retail, CN, institution and case labels;

2. review all label proofs and/or finished labels in accordance with Attachment 2 to assure that the label information agrees with the product represented. Discrepancies should be resolved with the processor. The CSI/CSO will identify any noted discrepancies in Block #13,

Remarks, on the NOAA Form 89-819, or by a note attached to the form, or directly on one copy of the label submitted, and sign the noted discrepancies;

3. determine that the corresponding specification used to prepare the product has been approved or is being submitted for approval with the label;

4. determine that specifications, and product samples if requested, are submitted in accordance with the instructions contained in Part I, Chapter 3, Section 08;

5. review and sign NOAA Form 89-819 after assuring it is completed in accordance with the instructions, and retain the Field Copy of the form in the office file until approval action has been completed; and

6. return the signed NOAA Form 89-819 to the establishment for submission to the appropriate Regional CSO, or the Approving Officer, DASS.

Note: One-Run Approval. The assigned CSI/CSO or supervisory CSO may give one-run approval for a plant to use a label only after reviewing the label in accordance with these instructions and receiving verbal approval from the Regional CSO or Approving Officer. The NOAA Form 89-819 must be completed for immediate submittal to the Regional CSO for the submitting region.

C. Regional Consumer Safety Officer and Approving Officer

1. Label Review and Approval or Temporary Approval or Disapproval.

a. Institutional and case labels will be reviewed by the appropriate Regional Consumer Safety Officer to determine compliance with the Fair Packaging and Labeling Act, Federal Food, Drug and Cosmetic Act, as amended, and other applicable labeling regulations. Retail and CN labels will be reviewed by the Approving Officer to determine compliance with the Fair Packaging and Labeling Act, Federal Food, Drug and Cosmetic Act, as amended, Nutritional Labeling and Education Act, and other applicable labeling regulations.

b. The Regional Consumer Safety Officer, or the Approving Officer will complete the portion of NOAA Form 89-819 designated "Action Taken," and sign and date the form. Copies will be distributed as follows:

(1) Original and Inspector Copy - To the USDC CSI/CSO stationed at the establishment submitting the labels or proofs. The CSI/CSO will forward the original to the processor, file the Inspector Copy, and discard the Field copy. Copies for HACCP-based Inspection establishments will be returned directly to the submitting establishment.

(2) DASS Office Copy - Retained by the Approving Officer, or submitted to DASS by the Regional Consumer Safety Officer.

(3) Regional Office Copy - Retained by the Regional CSO or will be forwarded to the Regional CSO by DASS.

2. Label Cancellation.

The Regional CSO or the Approving Officer will assure that requests for label cancellation result in proper notation of such labels in the master files. Distribution of NOAA Form 89-819 for cancellation will be the same as that for label approval actions depending on the type label, (retail or nonretail).

VI. LABEL AND PROOF STATUS AS DEFINED BY ACTION TAKEN.

A. Proofs.

1. Proofs submitted for review that comply with the labeling regulations will be “Approved To Print As Is.” When the proof is printed, the finished label must be submitted for final approval.
2. Proofs submitted that are not in compliance with the labeling regulations will be “Approved To Print With Changes Noted.” When printed with the corrections, finished label must be submitted for final approval.

B. Labels.

1. Labels that are submitted and are in compliance with all labeling laws and regulations will be given a “Final Approval.” This approval is good for five years, then the labels must be re-submitted for approval to assure and validate that the labels are current and in use.

2. Labels submitted that are not in compliance with the labeling laws and regulations, standards of identity or other applicable regulations will be given a “Temporary Approval” for minor compliance provided that the noncompliance does not warrant a “Disapproval.” (Disapproval is identified below). The temporary approval is granted to allow establishments time to correct the label and re-submit the corrected label.

3. Maximum time limits for “Temporary Approval” are:

   a. four months for flat labels (i.e., those affixed to cartons, packages and cases);

   b. nine months for printed bags; and

   c. twelve months for printed cartons.

4. Temporarily approved labels may be re-submitted for an extension of the temporary approval. The processor must provide information on the stock remaining and the expected usage rate before an extension will be granted. Further, noncompliance may warrant that the label be over-stickered before any additional use of the label is allowed. This condition will be noted on the NOAA Form 89-819, identifying the time-frame for over-stickering.

5. Labels in noncompliance will be given a “Disapproval” for the following reasons:

   a. Labels bearing USDC Inspection Marks that do not accurately convey the degree of inspection effort. Example, a label bearing a PUFI Mark while the product is lot inspected.

   b. Labels bearing USDC Inspection Marks or references to USDC Inspection that are not approved by the “Policy and Guidelines for Advertising USDC Inspection Marks.”

c. Labels that fail to bear mandatory nutrition labeling and that are not exempt by the regulations.

d. Labels bearing ingredients statements that do not declare or disclose all ingredients identified by the specification for that product or that fail to declare the use of flavors, artificial colors, preservatives, and/or food additives, or that substantially misidentifies an ingredient to the point that it is false or misleading.

e. Labels that bear nutrient content claims when the claim does not conform to the regulations for nutrient content claims.

f. Label that bear net quantity of content statements without metric declaration of the content.

g. Labels bearing identity statements that do not conform to the standard of identity for that product.

h. Labels bearing a statement of identity that does not identify the product by common or usual name.

i. Labels that are required to bear Country of Origin labeling and fail to disclose the country of origin or misrepresent the country of origin.

j. Labels that utilize an information panel and fail to provide all required information without intervening material (information not required).

k. Labels that provide nutrition information and fail to declare the correct serving size in relation to the reference serving size, resulting in a misrepresentation of the nutrient levels and erroneous nutrition information.

l. Labels that contain four or more violations of the requirements contained in the subparts of 21 CFR 101 or other applicable regulations.

VII. LABEL REVIEW/APPROVAL CONDITIONS THAT WARRANT BILLING

A. Rate. As established by NOAA Inspection Manual 25, Part I, Chapter 1, Section 16, establishments submitting labels for review/approval may be charged for the time required. The rate for label review/approval is established as Type III, and the minimum charge is established as one half hour.

B. Conditions. The following are the current conditions that warrant charging for label review/approval:

1. Nonapplicant review and opinion on labels.

2. Consultation on labels and specifications for contract and noncontract establishments.

3. Potential clients of the program that have labels reviewed or approved that do not subsequently enter the program.

4. Labels that must be disapproved after the proofs were given initial approval to print as is, or approval to print with changes noted.

5. Labels that are not corrected after submittal of proofs for review.

6. Labels that are given the maximum time (VI.B.3.) on a temporary approval and the establishment requests an extension to continue the use of the label.

7. Fax submission of labels for one-run approvals.

VIII. ABBREVIATED LABEL REVIEW/APPROVAL SYSTEM

A. Responding to establishment requests to improve and expedite label approval and to make such establishments more responsible for their labels, the following procedures were developed to follow closely the HACCP-based Inspection Program. Establishments capable of developing labels in compliance with the applicable labeling laws and regulations will have the opportunity to participate in the abbreviated label review/approval system. Such a system will not require pre-approval for all labels by NMFS prior to use.

B. Establishment Requirement Procedures.

1. Establishments must request in writing, admission to this system. Letters requesting admission are addressed to the Approving Officer (address on page 3 of this manual release).

2. Establishments must provide in the request letter, the name of the person(s) developing the labels for the establishment and include information on the background and qualifications of such person(s) that provide evidence of the individual(s) competency to develop complying labels.

C. NMFS Responsibility.

1. The Approving Officer will review the letters and history of label submittals. History refers to no more than the past year submittals by the requesting establishment.

2. The Approving Officer will provide formal written notice to the establishment indicating acceptance of the establishment into the system.

3. The Approving Officer will notify the appropriate Regional CSO of the establishment's acceptance into the system.

D. System Operation.

1. Labels (retail, institutional, case and CN) must be separated and submitted as identified in V, Submittal Instructions.

2. CN labels will not be included under this system. Food and Nutrition Services (FNS) must pre-approve all CN labels and require NMFS approval prior to their review/approval.

3. Levels.

a. Level III - Thirty labels of each group, excluding CN, must be submitted and undergo a one-of-one review for compliance with all applicable laws and regulations regarding label approval. If all labels of the

group are in compliance, i.e., no label is disapproved or given temporary approval, the establishment moves to the next higher level (Level II). Establishments under Level III must have labels approved prior to use. If an establishment has labels that are disapproved or temporarily approved, they remain in Level III and repeat the process. An establishment could move to Level II for institutional labels and remain in Level III for retail labels.

b. Level II - Thirty additional labels are reviewed at a one-of-three frequency and are not required to be approved prior to use provided the labels have been submitted to the appropriate review/approval authority. Of the ten labels reviewed, no more than one label considered to be temporarily approved will be permitted in order for the establishment to move to the next higher level (Level I). If one label in the ten is considered disapproved, the establishment falls back to the entry level (Level III). If two labels of the ten reviewed are temporarily approved, the establishment moves back to Level III.

c. Level I - Once the establishment reaches this level, labels will be reviewed at a frequency of one-of-five in lots of 50. If all labels are in compliance or one label in the ten is temporarily approved, the establishment remains in Level I and repeats the process for Level I. If one label is considered to be disapproved, the establishment falls back to Level III. If two labels in the ten reviewed are considered to be temporarily approved, the establishment falls back to Level II.

d. Decision Criteria

Abbreviated Label Review/Approval System			
Level	Labels Reviewed	Total Submitted	Qualifications
III	30 labels 1 of 1 review/group	30/group	If all labels (per group) are in compliance move to Level II. If any labels is disapproved or given Temporary Approval, remain in Level III and repeat.

II	10 labels 1 of 3 per group	30/group	If all labels (per group) are in compliance or one is given Temporary Approval, move to Level I. If one or more labels is given disapproval, move back to Level III. If two or more labels are given Temporary Approval, move back to entry Level III.
I	10 labels 1 of 5 per group	50/group	If all labels are in compliance or one label is given Temporary Approval, remain in Level I, repeat Level I review. If one or more labels are given disapproval, fall back to Level III. If two or more labels are given Temporary Approval, ball back to Level II and repeat Level II.

4. Removal from the System.

If an establishment falls to Level III twice after entering the system; or if they remain in the entry level after two attempts; or if they fall to a lower level four times; a determination will be made as to the suitability of the establishment remaining in the system.

NOAA FORM 89-819

U.S. DEPARTMENT OF COMMERCE

1. DATE SUBMITTED

PRESCRIBED BY INSPECTION MANUAL 25
ADMINISTRATION
(10-91)

NATIONAL OCEANIC AND ATMOSPHERIC

NATIONAL SEAFOOD INSPECTION PROGRAM

2. PLANT CODE(s)

SPECIFICATION AND LABEL SUBMITTAL ACTION REQUEST

INSTRUCTIONS - Please print or complete by typewriter. Submit a set of 5 specifications and/or labels with each product label indicated on form. All copies except field copy are to be submitted to the address below for action. Field copy to be retained by requestor until specifications and/or labels are returned by Approving Officer.

3. PROCESSOR OR PACKER (Name, Address and Phone Number)

TO: National Seafood Inspection Program
Documentation Approval and Supply Services Section
3207 Frederic Street, Suite B
P.O. Drawer 1207
Pascagoula, MS 39568-1207

4. DISTRIBUTOR (Name and full address)

USDC No. (Item 5) to be assigned by Approving Officer. Indicate USDC No. of approved specifications or labels when submitting replacements with minor changes, or when submitting for verification or cancellation. Indicate primary logo, packer or distributor name, or other identification for Item 6. Use numbers only for Item 9: 1 - No. Shield, 2 - Combination Grade A & PUFI, 3 - PUFI Mark, 4 - Grade A, 5 - Lot Inspected Mark.

5. USDC NO.		6. PRODUCT IDENTIFICATION (Brand and Identifying numbers if any)	7. COMMODITY (Use official terminology including type, style and size; Indicate in ounces or count/pounds. Enter commodity code and species code)			8. CONTENT OR NET WT.	9. SHIELD CODE
LABEL	SPEC.			Comm. Code	Species Code		

10. USDC INSPECTOR *(Signature)* .

COMPANY OFFICIAL *(Signature)*

11. HAVE SPECIFICATIONS AND/OR LABELS BEEN REVIEWED FOR COMPLIANCE WITH USDC AND FDA REGULATIONS?

BY INSPECTOR? ☐ YES ☐ NO BY FIELD INSPECTION OFFICER? ☐ YES ☐ NO

12. ACTION REQUESTED ☐ LABEL/SPEC. REVIEW ☐ NEW LABEL SKETCH/PROOF REVIEW ☐ NEW LABEL APPROVAL (Final)
☐ NEW SPEC. APPROVAL (FINAL) ☐ REPLACEMENT SPEC. OR LABEL ☐ CANCEL APPROVAL ☐ OTHER (Specify in remarks)
☐ USDA/FNS (CN) LABEL OR SPECS ACTION ☐ EXTEND TEMPORARY APPROVAL (Specify reason in remarks)

NOTE: APPROVAL BY THE USDC IS BASED ON THE INFORMATION SUPPLIED AND DOES NOT IMPLY CONCURRENCE OR ACCEPTANCE BY OTHER FEDERAL, STATE OR LOCAL GOVERNMENTAL AGENCIES UNLESS SPECIFICALLY NOTED, NOR DOES IT RELIEVE THE COMPANY FROM COMPLIANCE WITH OTHER APPLICABLE LAWS, REGULATIONS OR RULINGS. THIS APPROVAL BECOMES VOID IF CHANGES ARE MADE IN THE SPECIFICATION OR LABEL WITHOUT THE CONCURRENCE OF THE USDC APPROVING OFFICER.

13. **REMARKS** ***(Please initial)***

TO BE COMPLETED BY APPROVING OFFICE ONLY

PROOF APPROVED FOR PRINTING ☐ **AS IS** ☐ **WITH CHANGES NOTED**

☐ **TEMPORARY APPROVAL EXPIRES** _____

☐ **FINAL APPROVAL** ☐ **DISAPPROVED** ☐ **CANCELLED**

☐ **EXTENDS APPROVAL** ☐ **REVIEWED**

APPROVING OFFICER (*Signature)* **DATE**

USDA/FCS USE ONLY
SKETCH/PROOF **LABEL**
CONCURRENCE **NON-CONCURRENCE**
USDA APPROVAL *(Signature)* **DATE**

LABEL CHECKLIST

US Code as of: 01/05/99

Sec. 1621. Congressional declaration of purpose; use of existing facilities; cooperation with States

The Congress declares that a sound, efficient, and privately operated system for distributing and marketing agricultural products is essential to a prosperous agriculture and is indispensable to the maintenance of full employment and to the welfare, prosperity, and health of the Nation. It is further declared to be the policy of Congress to promote through research, study, experimentation, and through cooperation among Federal and State agencies, farm organizations, and private industry a scientific approach to the problems of marketing, transportation, and distribution of agricultural products similar to the scientific methods which have been utilized so successfully during the past eighty-four years in connection with the production of agricultural products so that such products capable of being produced in abundance may be marketed in an orderly manner and efficiently distributed. In order to attain these objectives, it is the intent of Congress to provide for (1) continuous research to improve the marketing, handling, storage, processing, transportation, and distribution of agricultural products; (2) cooperation among Federal and State agencies, producers, industry organizations, and others in the development and effectuation of research and marketing programs to improve the distribution processes; (3) an integrated administration of all laws enacted by Congress to aid the distribution of agricultural products through research, market aids and services, and regulatory activities, to the end that marketing methods and facilities may be improved, that distribution costs may be reduced and the price spread between the producer and consumer may be narrowed, that dietary and nutritional standards may be improved, that new and wider markets for American agricultural products may be developed, both in the United States and in other countries, with a view to making it possible for the full production of American farms to be disposed of usefully, economically, profitably, and in an orderly manner. In effectuating the purposes of this chapter, maximum use shall be made of existing research facilities owned or controlled by the Federal Government or by State agricultural experiment stations and of the facilities of the Federal and State extension services. To the maximum extent practicable marketing research work done under this chapter in cooperation with the States shall be done in cooperation with the State agricultural experiment stations; marketing educational and demonstrational work done under this chapter in cooperation with the States shall be done in cooperation with the State agricultural extension service; market information, inspection, regulatory work and other marketing service done under this chapter in cooperation with the State agencies shall be done in cooperation with the State departments of agriculture, and State bureaus and departments of markets.

US Code as of: 01/05/99

Sec. 1622. Duties of Secretary relating to agricultural products

The Secretary of Agriculture is directed and authorized:

- (a) Determination of methods of processing, packaging, marketing, etc.; publication of results
  To conduct, assist, and foster research, investigation, and experimentation to determine the best methods of processing, preparation for market, packaging, handling, transporting, storing, distributing, and marketing agricultural products: Provided, That the results of such research shall be made available to the public for the purpose of expanding the use of American agricultural products in such manner as the Secretary of Agriculture may determine.

- (b) Determination of costs
  To determine costs of marketing agricultural products in their various forms and through the various channels and to foster and assist in the development and establishment of more efficient marketing methods (including analyses of methods and proposed methods), practices, and facilities, for the purpose of bringing about more efficient and orderly marketing, and reducing the price spread between the producer and the consumer.

- (c) Improvement of standards of quality, condition, etc.; standard of quality for ice cream
  To develop and improve standards of quality, condition, quantity, grade, and packaging, and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices. Within thirty days after September 29, 1977, the Secretary shall by regulation adopt a standard of quality for ice cream which shall provide that ice cream shall contain at least 1.6 pounds of total solids to the gallon, weigh not less than 4.5 pounds to the gallon and contain not less than 20 percent total milk solids, constituted of not less than 10 percent milkfat. In no case shall the content of milk solids not fat be less than 6 percent. Whey shall not, by weight, be more than 25 percent of the milk solids not fat. Only those products which meet the standard issued by the Secretary may bear a symbol thereon indicating that they meet the Department of Agriculture standard for "ice cream".

- (d) Elimination of artificial barriers to free movement
  To conduct, assist, foster, and direct studies and informational programs designed to eliminate artificial barriers to the free movement of agricultural products.

- (e) Development of new markets
  To foster and assist in the development of new or expanded markets (domestic and foreign) and new and expanded uses and in the moving of larger quantities of agricultural products through the private marketing system to consumers in the United States and abroad.

- (f) Increasing consumer education
  To conduct and cooperate in consumer education for the more effective utilization and greater consumption of agricultural products: Provided, That no money appropriated under the authority of this chapter shall be used to pay for newspaper or periodical advertising space or radio time in carrying out the purposes of this section and subsection (e) of this section.

- (g) Collection and dissemination of marketing information
  To collect and disseminate marketing information, including adequate outlook information on a market-area basis, for the purpose of anticipating and meeting consumer requirements, aiding in the maintenance of farm income, and bringing about a balance between production and utilization of agricultural products.

- (h) Inspection and certification of products in interstate commerce; credit and future availability of funds; investment; certificates as evidence; penalties
  To inspect, certify, and identify the class, quality, quantity, and condition of agricultural products when shipped or received in interstate commerce, under such rules and regulations as the Secretary of Agriculture may prescribe, including assessment and collection of such fees as will be reasonable and as nearly as may be to cover the cost of the service rendered, to the end that agricultural products may be marketed to the best advantage, that trading may be facilitated, and that consumers may be able to obtain the quality product which they desire, except that no person shall be required to use the service authorized by this subsection. Any fees collected under this subsection, late payment penalties, the proceeds from the sales of samples, and interest earned from the investment of such funds shall be credited to the trust fund account that incurs the cost of the services provided under this subsection and shall remain available without fiscal year limitation to pay the expenses of the Secretary incident to providing such services. Such funds may be invested by the Secretary in insured or fully collateralized, interest-bearing accounts or, at the discretion of the Secretary, by the Secretary of the Treasury in United States Government debt instruments. Any official certificate issued under the authority of this subsection shall be received by all officers and all courts of the United States as prima facie evidence of the truth of the statements therein contained. Whoever knowingly shall falsely make, issue, alter, forge, or counterfeit any official certificate, memorandum, mark, or other identification, or device for making such mark or identification, with respect to inspection, class, grade, quality, size, quantity, or condition, issued or authorized under this section or knowingly cause or procure, or aid, assist in, or be a party to, such false making, issuing, altering, forging, or counterfeiting, or whoever knowingly shall possess, without promptly notifying the Secretary of Agriculture or his representative, utter, publish, or use as true, or cause to be uttered, published, or used as true, any such falsely made, altered, forged, or counterfeited official certificate, memorandum, mark, identification, or device, or whoever knowingly represents that an agricultural product has been officially inspected or graded (by an authorized inspector or grader) under the authority of this section when such commodity has in fact not been so graded or inspected shall be fined not more than $1,000 or imprisoned not more than one year, or both. Shell eggs packed under the voluntary

grading program of the Department of Agriculture shall not have been shipped for sale previous to being packed under the program, as determined under a regulation promulgated by the Secretary.

- (i) Development of facilities for assembling, processing, transporting, etc.
  To determine the needs and develop or assist in the development of plans for efficient facilities and methods of operating such facilities for the proper assembly, processing, transportation, storage, distribution, and handling of agricultural products.
  - (j) Improvement of transportation facilities and rates
    To assist in improving transportation services and facilities and in obtaining equitable and reasonable transportation rates and services and adequate transportation facilities for agricultural products and farm supplies by making complaint or petition to the Interstate Commerce Commission, the Maritime Commission,, (FOOTNOTE 1) or other Federal or State transportation regulatory body, or the Secretary of Transportation, with respect to rates, charges, tariffs, practices, and services, or by working directly with individual carriers or groups of carriers.
  - (k) Collection and dissemination of marketing statistics
    To collect, tabulate, and disseminate statistics on marketing agricultural products, including, but not restricted to statistics on market supplies, storage stocks, quantity, quality, and condition of such products in various positions in the marketing channel, utilization of such products, and shipments and unloads thereof.
  - (l) Development of procurement standards and specifications
    To develop and promulgate, for the use and at the request of any Federal agency or State, procurement standards and specifications for agricultural products, and submit such standards and specifications to such agency or State for use or adoption for procurement purposes.
  - (m) Promotion of research for handling, storing, preserving, etc.
    To conduct, assist, encourage, and promote research, investigation, and experimentation to determine the most efficient and practical means, methods, and processes for the handling, storing, preserving, protecting, processing, and distributing of agricultural commodities to the end that such commodities may be marketed in an orderly manner and to the best interest of the producers thereof.
  - (n) General research, services, and activities
    To conduct such other research and services and to perform such other activities as will facilitate the marketing, distribution, processing, and utilization of agricultural products through commercial channels.

Footnotes

[1] So in original.

US Code as of: 01/23/00

Sec. 742a. Declaration of policy

The Congress declares that the fish, shellfish, and wildlife resources of the Nation make a material contribution to our national economy and food supply, as well as a material contribution to the health, recreation, and well-being of our citizens; that such resources are a living, renewable form of national wealth that is capable of being maintained and greatly increased with proper management, but equally capable of destruction if neglected or unwisely exploited; that such resources afford outdoor recreation throughout the Nation and provide employment, directly or indirectly, to a substantial number of citizens; that the fishing industries strengthen the defense of the United States through the provision of a trained seafaring citizenry and action-ready fleets of seaworthy vessels; that the training and sport afforded by fish and wildlife resources strengthen the national defense by contributing to the general health and physical fitness of millions of citizens; and that properly developed, such fish and wildlife resources are capable of steadily increasing these valuable contributions to the life of the Nation.
The Congress further declares that the fishing industry, in its several branches, can prosper and thus fulfill its proper function in national life only if certain fundamental needs are satisfied by means that are consistent with the public interest and in accord with constitutional functions of governments. Among these needs are:

- (1) Freedom of enterprise - freedom to develop new areas, methods, products, and markets in accordance with sound economic principles, as well as freedom from unnecessary administrative or legal restrictions that unreasonably conflict with or ignore economic needs;

- (2) Protection of opportunity - maintenance of an economic atmosphere in which domestic production and processing can prosper; protection from subsidized competing products; protection of opportunity to fish on the high seas in accordance with international law;

- (3) Assistance - assistance consistent with that provided by the Government for industry generally, such as is involved in promoting good industrial relations, fair trade standards, harmonious labor relations, better health standards and sanitation; and including, but not limited to -
    - (a) services to provide current information on production and trade, market promotion and development, and an extension service,
    - (b) research services for economic and technologic development and resource conservation, and

(c) resource management to assure the maximum sustainable production for the fisheries.

The Congress further declares that the provisions of this Act are necessary in order to accomplish the objective of proper resource development, and that this Act shall be administered with due regard to the inherent right of every citizen and resident of the United States to engage in fishing for his own pleasure, enjoyment, and betterment, and with the intent of maintaining and increasing the public opportunities for recreational use of our fish and wildlife resources, and stimulating the development of a strong, prosperous, and thriving fishery and fish processing industry.

[Reorg. Plan No. 4 of 1970, 3 C.F.R. xx (1970), *reprinted in* 84 Stat. 2090-93 (1970), *and in* 35 Fed. Reg. 15627-30 (1970), *and reprinted with amendments in* 5 U.S.C. app. at 1557-61 (1994)]

Reorganization Plan No. 4 of 1970

Prepared by the President and transmitted to the Senate and the House of Representatives in Congress assembled, July 9, 1970, pursuant to the provisions of chapter 9 of title 5 of the United States Code.[1]

[1]Effective October 3, 1970, under the provisions of 5 U.S.C. 906.

NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION

SECTION 1. *Transfers to Secretary of Commerce*. The following are hereby transferred to the Secretary of Commerce

(a) All functions vested by law in the Bureau of Commercial Fisheries of the Department of the Interior or in its head, together with all functions vested by law in the Secretary of the Interior or the Department of the Interior which are administered through that Bureau or are primarily related to the Bureau, exclusive of functions with respect to (1) Great Lakes fishery research and activities related to the Great Lakes Fisheries Commission, (2) Missouri River Reservoir research, (3) the Gulf Breeze Biological Laboratory of the said Bureau at Gulf Breeze, Florida, and (4) Trans-Alaska pipeline investigations.

(b) The functions vested in the Secretary of the Interior by the Act of September 22, 1959 (Public Law 86-359, 73 Stat. 642, 16 U.S.C. 760e-760g; relating to migratory marine species of game fish).

(c) The functions vested by law in the Secretary of the Interior, or in the Department of the Interior or in any officer or instrumentality of that Department, which are administered through the Marine Minerals Technology Center of the Bureau of Mines.

(d) All functions vested in the National Science Foundation by the National Sea Grant College and Program Act of 1966 (80 Stat. 998), as amended (33 U.S.C. 1121 et seq.).

(e) Those functions vested in the Secretary of Defense or in any officer, employee, or organizational entity of the Department of Defense by the provision of Public Law 91-144, 83 Stat. 326, under the heading "Operation and maintenance, general" with respect to "surveys and charting of northern and northwestern lakes and connecting waters," or by other law, which come under the mission assigned as of July 1, 1969, to the United States Army Engineer District, Lake Survey, Corps of Engineers, Department of the Army and relate to (1) the conduct of hydrographic surveys of the Great Lakes and their outflow rivers, Lake Champlain, New York State Barge Canals, and the Minnesota-Ontario border lakes, and the compilation and publication of navigation charts, including recreational aspects, and the Great Lakes Pilot for the benefit and use of the public, (2) the conception, planning, and conduct of basic research and development in the fields of water motion, water characteristics, water quantity, and ice and snow, and (3) the publication of data and the results of research projects in forms useful to the Corps of Engineers and the public, and the operation of a Regional Data Center for the collection, coordination, analysis, and the furnishing to interested agencies of data relating to water

resources of the Great Lakes.

(f) So much of the functions of the transferor officers and agencies referred to in or affected by the foregoing provisions of this section as is incidental to or necessary for the performance by or under the Secretary of Commerce of the functions transferred by those provisions or relates primarily to those functions. The transfers to the Secretary of Commerce made by this section shall be deemed to include the transfer of authority, provided by law, to prescribe regulations relating primarily to the transferred functions.

SEC. 2. *Establishment of Administration*. (a) There is hereby established in the Department of Commerce an agency which shall be known as the National Oceanic and Atmospheric Administration, hereinafter referred to as the "Administration."

(b) There shall be at the head of the Administration the Administrator of the National Oceanic and Atmospheric Administration, hereinafter referred to as the "Administrator." The Administrator shall be appointed by the President, by and with the advice and consent of the Senate, and shall be compensated at the rate now or hereafter provided for Level III of the Executive Schedule Pay Rates (5 U.S.C. 5314).

(c) There shall be in the Administration a Deputy Administrator of the National Oceanic and Atmospheric Administration who shall be appointed by the President, by and with the advice and consent of the Senate, and shall be compensated at the rate now or hereafter provided for Level IV of the Executive Schedule Pay Rates (5 U.S.C. 5315). The Deputy Administrator shall perform such functions as the Administrator shall from time to time assign or delegate, and shall act as Administrator during the absence or disability of the Administrator or in the event of a vacancy in the office of Administrator.

(d) There shall be in the Administration an Associate Administrator of the National Oceanic and Atmospheric Administration who shall be appointed by the President , by and with the advice and consent of the Senate, and shall be compensated at the rate now or hereafter provided for Level V of the Executive Schedule Pay Rates (5 U.S.C. 5316). The Associate Administrator shall perform such functions as the Administrator shall from time to time assign or delegate, and shall act as Administrator during the absence or disability of the Administrator and Deputy Administrator. The office of Associate Administrator may be filled at the discretion of the President by appointment (by and with the advice and consent of the Senate) from the active list of the commissioned officers of the Administration in which case the appointment shall create a vacancy on the active list and while holding the office of Associate Administrator the officer shall have rank, pay, and allowances not exceeding those of a vice admiral.

(e) There shall be in the Administration three additional officers who shall perform such functions as the Administrator shall from time to time assign or delegate. Each such officer shall be appointed by the Secretary, subject to the approval of the President, under the classified civil service, shall have such title as the Secretary shall from time to time determine, and shall receive compensation at the rate now or hereafter provided for Level V of the Executive Schedule Pay Rates (5 U.S.C. 5316).

(f) The President may appoint in the Administration, by and with the advice and consent of the Senate, two commissioned officers to serve at any one time as the designated heads of two principal constituent organizational entities of the Administration, or the President may designate one such officer as the head of such an organizational entity and the other as the head of the commissioned corps of the Administration. Any such designation shall create a vacancy on the active list and the officer while serving under this subsection shall have the rank, pay, and allowances of a rear admiral (upper half).

(g) Any commissioned officer of the Administration who has served under (d) or (f) and is retired

while so serving or is retired after the completion of such service while serving in a lower rank or grade, shall be retired with the rank, pay, and allowances authorized by law for the highest grade and rank held by him; but any such officer, upon termination of his appointment in a rank above that of captain, shall, unless appointed or assigned to some other position for which a higher rank or grade is provided, revert to the grade and number he would have occupied had he not served in a rank above that of captain and such officer shall be an extra number in that grade.

SEC. 3. *Performance of transferred functions.* The provisions of sections 2 and 4 of Reorganization Plan No. 5 of 1950 (64 Stat. 1263) shall be applicable to the functions transferred hereunder to the Secretary of Commerce.

SEC. 4 *Incidental Transfers.* (a) So much of the personnel, property, records, and unexpended balances of appropriations, allocations, and other funds employed, used, held, available, or to be made available in connection with the functions transferred to the Secretary of Commerce by this reorganization plan as the Director of the Office of Management and Budget shall determine shall be transferred to the Department of Commerce at such time or times as the Director shall direct.

(b) Such further measures and dispositions as the Director of the Office of Management and Budget shall deem to be necessary in order to effectuate the transfers referred to in subsection (a) of this section shall be carried out in such manner as he shall direct and by such agencies as he shall designate.

(c) The personnel, property, records, and unexpended balances of the appropriations, allocations, and other funds of the Environmental Science Services Administration shall become personnel, property, records, and unexpended balances of the National Oceanic and Atmospheric Administration or of such other organizational entity or entities of the Department of Commerce as the Secretary of Commerce shall determine.

(d) The Commissioned Officer Corps of the Environmental Science Services Administration shall become the Commissioned Officer Corps of the National Oceanic and Atmospheric Administration. Members of the Corps, including those appointed hereafter, shall be entitled to all rights, privileges, and benefits heretofore available under any law to commissioned officers of the Environmental Science Services Administration, including those rights, privileges, and benefits heretofore accorded by law to commissioned officers of the former Coast and Geodetic Survey.

(e) Any personnel, property, records, and unexpended balances of appropriations, allocations, and other funds of the Bureau of Commercial Fisheries not otherwise transferred shall become personnel, property, records, and unexpended balances of such organizational entity or entities of the Department of the Interior as the Secretary of the Interior shall determine.

SEC. 5. *Interim Officers.* (a) The President may authorize any person who immediately prior to the effective date of this reorganization plan held a position in the executive branch of the Government to act as Administrator until the office of Administrator is for the first time filled pursuant to the provisions of this reorganization plan or by recess appointment, as the case may be.

(b) The President may similarly authorize any such person to act as Deputy Administrator and authorize any such person to act as Associate Administrator.

(c) The President may similarly authorize a member of the former Commissioned Officer Corps of the Environmental Science Services Administration to act as the head of one principal constituent organizational entity of the Administration.

(d) The President may authorize any person who serves in an acting capacity under the foregoing provisions of this section to receive the compensation attached to the office in respect of which he so

serves. Such compensation, if authorized, shall be in lieu of, but not in addition to, other compensation from the United States to which such person may be entitled.

SEC. 6. *Abolitions*. (a) Subject to the provisions of this reorganization plan, the following, exclusive of any functions, are hereby abolished:

(1) The Environmental Science Services Administration in the Department of Commerce (established by Reorganization Plan No. 2 of 1965, 79 Stat.1318), including the offices of Administrator of the Environmental Science Services Administration and Deputy Administrator of the Environmental Science Services Administration.

(2) The Bureau of Commercial Fisheries in the Department of the Interior (16 U.S.C. 742b), including the office of Director of the Bureau of Commercial Fisheries.

(b) Such provisions as may be necessary with respect to terminating any outstanding affairs shall be made by the Secretary of Commerce in the case of the Environmental Science Services Administration and by the Secretary of the Interior in the case of the Bureau of Commercial Fisheries.

[F.R. Doc. 70-13375; Filed Oct. 5, 1970; 8:45 a.m.]

questionnaire, Wuxi stated that it is not under the control of the PRC government. After submitting its section A response, Wuxi failed to submit any other information to the Department including its response to sections C and D of the antidumping questionnaire. Because Wuxi terminated its participation in this review, we have preliminarily determined that Wuxi is not entitled to a separate rate. Thus, we are preliminarily rescinding this new shipper review.

Any interested party may request a hearing within 30 days of publication of this notice in accordance with section 351.310(c) of the Department's regulations. Any hearing would normally be held 37 days after the publication of this notice, or the first workday thereafter, at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230. Individuals who wish to request a hearing must submit a written request within 30 days of the publication of this notice in the Federal Register to the Assistant Secretary for Import Administration, U.S. Department of Commerce, Room 1870, 14th Street and Constitution Avenue, NW., Washington, DC 20230. Requests for a public hearing should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and, (3) to the extent practicable, an identification of the arguments to be raised at the hearing. Unless otherwise notified by the Department, interested parties may submit case briefs within 21 days of the date of publication of this notice in accordance with 351.309(c)(ii) of the Department's regulations. As part of the case brief, parties are encouraged to provide a summary of the arguments not to exceed five pages and a table of statutes, regulations, and cases cited. Rebuttal briefs, which must be limited to issues raised in the case briefs, must be filed within five days after the case brief is filed. Further, we would appreciate it if parties submitting written comments would provide the Department with an additional copy of the public version of any such comments on diskette. If a hearing is held, an interested party may make an affirmative presentation only on arguments included in that party's case brief and may make a rebuttal presentation only on arguments included in that party's rebuttal brief. Parties should confirm by telephone the time, date, and place of the hearing 48 hours before the scheduled time.

The Department will issue the final results of this new shipper review, which will include the results of its analysis of issues raised in the briefs, within 90 days from the date of this preliminary result, unless the time limit is extended.

This new shipper review and this notice are published in accordance with sections 751(a)(2)(B) and 777(i)(1) of the Act.

January 18, 2002

Faryar Shirzad,

Assistant Secretary for Import Administration.

[FR Doc. 02–2033 Filed 1–25–02; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 012302B]

Proposed Information Collection; Comment Request; Seafood Inspection and Certification Requirements

AGENCY: National Oceanic and Atmospheric Administration (NOAA).

ACTION: Proposed information collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Pub. L. 104–13 (44 U.S.C. 3506 (c)(2)(A)).

DATES: Written comments must be submitted on or before March 29, 2002.

ADDRESSES: Direct all written comments to Madeleine Clayton, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6086, 14th and Constitution Avenue NW, Washington DC 20230 (or via Internet at MClayton@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Rita Creitz, F/SF6, Room 15341, 1315 East-West Highway, Silver Spring, MD 20910–3282 (phone 301–713–2355, ext. 155).

SUPPLEMENTARY INFORMATION:

I. Abstract

The National Marine Fisheries Service (NMFS) operates a voluntary fee-for-service seafood inspection program (Program) under the authorities of the Agricultural Marketing Act of 1946, as amended, the Fish and Wildlife Act of 1956, and the Reorganization Plan No. 4 of 1970.

The regulations for the Program are contained in 50 CFR Part 260. The program offers inspection grading and certification services, including the use of official quality grade marks which indicate that specific products have been Federally inspected. In addition, the NMFS inspection program is the only Federal entity that establishes quality grade standards for seafood marketed in the United States. Qualified participants are permitted to use the program's official quality grade marks on their products to facilitate trade of fishery products.

Participants in the inspection program are requested to submit specific information pertaining to the type of inspection service requested [Sec. 260.15]. In all cases, applicants provide the program information regarding the type of products to be inspected, the quantity, and location of the product. There are also application requirements if there is an appeal of previous inspection results [Sec. 260.36]. Participants requesting regular inspection services on a contractual basis also submit a contract [Sec. 260.96]. Participants interested in using official grade marks are required to submit product labels and specifications for review and approval to ensure compliance with mandatory labeling regulations established by the U.S. Food and Drug Administration as well as proper use of the Program's marks [Sec. 260.97 (c)(12) and (13)].

Current regulations state requirements for approval of drawings and specifications prior to approval of facilities [Sec. 260.96 (b) and (c)]. There are no respondents under this section. The Program will amend this part of the regulations in a future action.

In July 1992, NMFS announced new inspection services, which were fully based on guidelines recommended by the National Academy of Sciences, known as Hazard Analysis Critical Control Point (HACCP). The information collection requirements fall under Sec. 260.15 of the regulations. These guidelines required that a facility's quality control system have a written plan of the operation, identification of control points with acceptance criteria and a corrective action plan, as well as identified personnel responsible for oversight of the system. HACCP requires continuing monitoring and recordkeeping by the facility's personnel.

Although HACCP involves substantial self-monitoring by the industry, the HACCP-based program is not a self-certification program. It relies on unannounced system audits by NMFS. The frequency of audits is determined

by the ability of the firm to monitor its operation. By means of these audits, NMFS reviews the records produced through the program participant's self-monitoring. The audits determine whether the participant's HACCP-based system is in compliance by checking for overall sanitation, accordance with good manufacturing practices, labeling, and other requirements. In addition, in-process reviews, end-product sampling, and laboratory analyses are performed by NMFS at frequencies based on the potential consume risk associated with the product and/or the firm's history of compliance with the program's criteria.

The information collected is used to determine a participant's compliance with the program. The reported information, a HACCP plan, is needed only once. Other information is collected and kept by the participant as part of its routine monitoring activities. NMFS audits the participant's records on unannounced frequencies to further determine compliance.

II. Method of Collection

Information will be obtained via telephone, fax, hard-copy submission, or audit conducted by NMFS personnel.

III. Data

OMB Number: 0648–0266.

Form Number: NOAA Forms 89–800, 89–814, and 89–819.

Type of Review: Regular submission.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 7,082.

Estimated Time Per Response: 5 minutes for an application of inspection services; 5 minutes for an application for an appeal; 5 minutes for submitting a contract; 30 minutes to submit a label and specification; 105 hours for a Hazard Analysis Critical Control Point (HACCP) plan; and 80 hours for HACCP monitoring and recordkeeping.

Estimated Total Annual Burden Hours: 13,065.

Estimated Total Annual Cost to Public: $3,579.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 17, 2002.

Madeleine Clayton,

Departmental Paperwork Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 02–2001 Filed 1–25–02; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 012202B]

Proposed Information Collection; Comment Request; Highly Migratory Species Vessel Marking and Gear Marking

AGENCY: National Oceanic and Atmospheric Administration (NOAA).

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Pub. L. 104-13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before March 29, 2002.

ADDRESSES: Direct all written comments to Madeleine Clayton, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6086, 14th and Constitution Avenue NW, Washington DC 20230 (or via Internet at MClayton@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Christopher Rogers at the National Marine Fisheries Service (NMFS) Highly Migratory Species Management Division, 1315 East West Highway, Silver Spring, MD 20910, or by e-mail at christopher.rogers@noaa.gov or phone at 301–713–2347.

SUPPLEMENTARY INFORMATION:

I. Abstract

Under regulations at 50 CFR 635.6 fishing vessels permitted for Atlantic Highly Migratory Species must display their official vessel numbers on their vessels to assist law enforcement in monitoring fishing and other activities. Flotation devices attached to certain fishing gear must also be marked with the vessel's number to identify catch that is buoyed. This requirement is also necessary for law enforcement purposes.

II. Method of Collection

There is no form under this requirement. Official vessel numbers or permit numbers issued to vessel operators are marked on the vessel and on flotation gear.

III. Data

OMB Number: 0648-0373.

Form Number: None.

Type of Review: Regular submission.

Affected Public: Business or other for-profit organizations, individuals or households.

Estimated Number of Respondents: 8,051.

Estimated Time Per Response: 45 minutes to mark a vessel, 15 minutes to mark a float.

Estimated Total Annual Burden Hours: 7,176.

Estimated Total Annual Cost to Public: $161,020.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 17, 2002.

Madeleine Clayton,

Departmental Paperwork Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 02–2003 Filed 1–25–02; 8:45 am]

BILLING CODE 3510–22–S